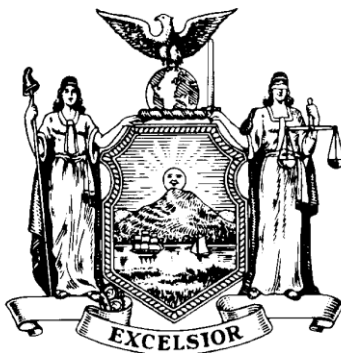


State of New York
Offices of the Inspector General



Investigation of New York State Department of
Corrections and Community Supervision
Incarcerated Individual Drug Testing Program

January 2022

Lucy Lang
Inspector General

EXECUTIVE SUMMARY

On September 19, 2019, the New York State Department of Corrections and Community Supervision (DOCCS) informed the Offices of the New York State Inspector General that its newly acquired incarcerated individuals¹ drug testing system might be falsely indicating positive results when testing for the opioid buprenorphine. This drug testing system was procured by DOCCS from the Microgenics Corporation (Microgenics) and installed in DOCCS' facilities beginning in January 2019.²

From January through August 2019, incarcerated individuals found to have positive drug test results at a disciplinary hearing received significant—and in some cases ultimately undeserved—punishments that jeopardized their rehabilitation and release, including:

- Solitary confinement in a Special Housing Unit (SHU)³
- Confinement to one's cell (keeplock)
- Delays in parole eligibility
- Loss of privileges including receipt of packages, commissary, and telephone use
- Loss of access to prison rehabilitation programs
- Loss of “good time” and family visitation rights
- Missed scheduled parole interviews

Further, disciplinary matters concerning drug use can adversely affect Board of Parole decisions and the granting of parole.

Upon receiving the complaint from DOCCS, the Inspector General immediately commenced an investigation into the matter. This investigation included more than 40 interviews of witnesses including DOCCS staff and incarcerated individuals, toxicologists, and Microgenics representatives, and the review of tens of thousands of documents including drug test results, disciplinary records, DOCCS emails, contracts, policies, and manufacturer specifications for drug tests and equipment. Additionally, dozens of hours of recorded

¹ Per Chapter 322 of the Laws of 2021, the terms “inmate” and “inmates” have been replaced in this report with the words “incarcerated individual” and “incarcerated individuals.” See, <https://www.nysenate.gov/legislation/bills/2021/s3332>.

² Microgenics Corporation is a wholly-owned subsidiary of Thermo Fisher Scientific Inc. See, <https://www.sec.gov/Archives/edgar/data/97745/000009774519000007/tmo201810kex21.htm>. Microgenics Corporation and Thermo Fisher Scientific Inc. are referred to as one entity in this report.

³ New York Code of Rules and Regulations, Title 7, Part 1, § 1.5(v) defines such confinement as “segregated confinement.”

disciplinary hearings were reviewed. The Inspector General also retained the services of Elizabeth Spratt M.S., F-ABFT⁴, an expert in toxicology, to review and verify the findings in this investigation.

Given the possible implications for incarcerated individuals, the Inspector General advised DOCCS in late 2019 to immediately cease all adverse action against incarcerated individuals for any positive drug test results until confirmatory testing from an independent outside laboratory could be obtained.⁵

DOCCS' Urinalysis Testing Policy⁶ mandates that if a screening test produces a positive result, a second test must be performed on the same sample. If both produce positive results, a misbehavior report may be issued against the incarcerated individual, with the test results used as evidence in a subsequent disciplinary hearing.

In practice, however, DOCCS would initially test an incarcerated individual's urine sample using the Microgenics test. When a test produced a positive result, DOCCS then merely retested that same urine sample using the same Microgenics test, instrument, and method. This process was contrary to the clear and prominent instructions provided with Microgenics test kits that require confirmatory testing to be done using a "more specific alternative" method.

The Inspector General found several examples of impacted incarcerated individuals raising concerns about their drug test results with DOCCS and Microgenics personnel:

- A woman at Albion Correctional Facility, who had never tested positive for drug use during her then more than two-year incarceration with DOCCS, asserted that a January 2019 drug test wrongly indicated that synthetic cannabinoids had been detected in her urine sample. Because of this and a subsequent Microgenics test, she was confined to her cell for 40 days and solitary confinement for 45 days. She lost her prison job and coveted housing assignment, and lost privileges including recreation time, receipt of packages, and telephone use for a total of 105 days. Additionally, she lost the privilege to participate in DOCCS' Family Reunion Program and therefore was denied the continuation of visits with her three children.
- Two Attica Correctional Facility incarcerated individuals tested positive for drug use in February 2019. Both had served lengthy terms with DOCCS and

⁴ See Spratt's resume and curriculum vitae attached to this report as Addendum 1.

⁵ See attached November 5, 2019 and December 31, 2019 letters from the Inspector General to DOCCS acting Commissioner Annucci.

⁶ DOCCS Directive 4937, Urinalysis Testing (December 27, 2018).

never previously tested positive for drugs while incarcerated. The first man, then incarcerated with DOCCS for almost a decade and a participant in DOCCS' Alcohol and Substance Abuse Treatment Program, tested positive for buprenorphine. The second man, who was incarcerated since 1984 and participated in DOCCS' Family Reunion Program, tested positive for synthetic cannabinoids. Both men were confined to their cells pending a disciplinary hearing. Ultimately, their misbehavior reports were dismissed and expunged from their records due to technical errors.

- An incarcerated individual who tested positive for buprenorphine in February 2019 questioned a Microgenics representative about possible cross-reactions with over-the-counter medications. The representative wrongly advised the individual that over-the-counter drugs would not cause a false positive and “anything that would cause a positive would be some sort of variation of buprenorphine or . . . something chemically related.” Nevertheless, this individual was found guilty and sentenced to 180 days in SHU with loss of recreation, package privileges, telephone and commissary privileges and recommended loss of 30 days of good time.
- A woman who upon her admission to DOCCS' Shock Incarceration Program at Lakeview Shock Incarceration Facility in August 2019 asserted that a drug test wrongly indicated that synthetic cannabinoids had been detected in her urine sample. Because of this and a subsequent Microgenics test, she lost privileges including visitation, recreation time, receipt of packages, and telephone use for a total of 30 days. Most notably, she was removed from the Shock program, which if she completed without incident would have made her likely eligible to be released within six months. Instead, she was not released until September 2020.
- In March 2019, an incarcerated individual questioned a Microgenics representative about the reliability of the preliminary drug screening tests. This individual, who denied using buprenorphine, had never failed a urine screening test while incarcerated with DOCCS. The Microgenics representative advised the individual that the test was 99.9 percent accurate, and he could not recall ever seeing a false positive result. The individual was found guilty and ultimately sentenced to 40 days of cell confinement, 75-days loss of recreation and package, telephone, and commissary privileges, and recommended loss of two months of good time.

The Inspector General's investigation found multiple shortcomings in the drug testing program that potentially impacted incarcerated individuals' rights and due process including:

- DOCCS disciplined incarcerated individuals based solely on the results of preliminary drug screening tests. These preliminary screening tests were not confirmed by more specific alternative tests as is required by Microgenics' drug test instructions.
- DOCCS failed to take prompt corrective action upon learning that some incarcerated individuals had been charged with drug violations and punished due to false positive drug screening test results

- DOCCS improperly procured its drug testing systems and services
- DOCCS failed to adequately oversee and train staff utilizing Microgenics' drug testing systems
- DOCCS experienced various administrative failures, which prevented the proper operation of the Incarcerated Individual Drug Testing Program
- Microgenics withheld information from DOCCS concerning false positive test results and research involving its drug testing systems and provided misleading and inconsistent statements during disciplinary hearings.

Specifically, the Inspector General's investigation found that in January 2019, DOCCS began using drug tests and instruments purchased from Microgenics to test urine samples of incarcerated individuals for the presence of prohibited substances including buprenorphine and synthetic cannabinoids, among others. Soon after implementation of these new tests, complaints from incarcerated individuals of false positive drug test results increased, including complaints from long-incarcerated individuals who had never before tested positive for illegal drugs while imprisoned. In a limited review of six positive samples using Microgenics' tests, two outside laboratories later determined four of the six positive test results were incorrect.

Microgenics' drug tests contain written instructions, which require that following a preliminary drug screening test, a "more specific alternative chemical method must be used to obtain a confirmed analytical result." These more specific alternative tests are typically performed by outside laboratories and can precisely identify and quantify drugs in urine samples thereby eliminating any false positive preliminary drug screening test results, which may be caused by cross-reacting substances or other factors.

During the period that DOCCS used Microgenics' drug testing systems in its facilities, 2,199 incarcerated individuals tested positive for buprenorphine. Based on the results of these preliminary drug screening tests, DOCCS charged and punished 1,632 incarcerated individuals.⁷ Punishment included solitary confinement in SHU, confinement in one's cell (keeplock), delays in parole eligibility and/or release, and/or the loss of privileges such as the receipt of packages, commissary, telephone use, and participation in the Family Reunion Program and other programs.

⁷ According to DOCCS, of the incarcerated individuals who tested positive for buprenorphine, 1,280 were punished with confinement and the remaining 352 received some other form of punishment. DOCCS was unable to verify whether punishment was meted out, in part or entirely, due to the positive drug test and/or other misbehavior.

The investigation also found DOCCS unreasonably relied on three-decade old case law—with distinct holdings based on another manufacturer’s drug test and methodology—to justify forgoing confirmatory testing of Microgenics’ drug test results. The court in that case did not consider the possibility that urine samples might contain cross-reacting substances that would trigger false-positive results. Nonetheless, the court concluded that this different manufacturer’s drug screening test results were reliable enough to satisfy due process concerns without the need for confirmatory testing. Given the inapplicable case law, and in light of the confirmed cases of drug testing errors with Microgenics’ systems, DOCCS should obtain confirmatory testing of all positive preliminary drug screening test results.

This decision to forgo confirmatory testing of Microgenics’ drug screening tests was largely promoted by just two individuals—the then administrator of the Incarcerated Individual Drug Testing Program and a Microgenics salesperson. Although neither the program administrator nor the salesperson had the education or training to conduct the necessary legal and scientific reviews required for a decision of this magnitude, they also revised DOCCS’ drug testing policy to support the use of Microgenics systems. Moreover, DOCCS provided no evidence of any scientific evaluation or substantive legal review of this matter. The investigation was unable to determine if DOCCS’ executive staff and commissioner were specifically apprised of this issue.

The Inspector General further found that a former DOCCS associate commissioner failed to take prompt corrective action after discovering that at least five incarcerated individuals had been wrongfully charged and punished for drug violations. In August 2019, the associate commissioner, while reviewing complaints of false drug test results, provided an outside laboratory with urine samples from six incarcerated individuals who had tested positive for buprenorphine using Microgenics’ drug screening tests. The outside laboratory found no detectable buprenorphine in five of the six samples. However, the associate commissioner took no action to remedy the matter and claimed that he did not recall if he had reported the testing errors to the acting commissioner or other executives.

The investigation also found that DOCCS procured its drug testing systems and services likely in violation of State Finance Law. Although State Finance Law provides a series of steps that must be taken when agencies seek to purchase commodities and services, DOCCS has historically failed to take these steps when purchasing drug testing systems. DOCCS also

entered into lease agreements for drug testing instruments in apparent violation of State Finance Law. In addition, the investigation found that DOCCS did not perform due diligence when contracting with Microgenics for its drug testing systems, failing to understand that such tests were merely preliminary screening tests that would require additional confirmatory testing.

DOCCS also committed various administrative failures in the Incarcerated Individual Drug Testing Program, which hindered the proper operation of the program. These included the failure by testing officers to enter all required information into a central disciplinary tracking database and to consistently consult medical staff on possible cross-reacting drugs—actions required by policy. Also, the investigation found DOCCS did not adequately train drug testing staff and hearing officers on the drug tests and instruments.

The investigation found that Microgenics failed to disclose to DOCCS issues it had discovered with its urinalysis tests, and Microgenics representatives provided incorrect and misleading information during DOCCS' disciplinary hearings. Indeed, when Microgenics learned that its buprenorphine test had produced four false positive results when testing six urine samples from DOCCS incarcerated individuals, it did not advise DOCCS of these results. And when Microgenics internal research revealed that one of its drug tests was susceptible to cross-reactivity with a common medication and another substance and might thereby produce false positive results, Microgenics again did not advise DOCCS of this fact.⁸ Moreover, when Microgenics representatives provided responses to questions asked by incarcerated individuals during disciplinary hearings, the information provided was sometimes misleading and incorrect. In fact, the Inspector General found while reviewing approximately 30 disciplinary hearing recordings that Microgenics representatives never advised incarcerated individuals that its drug screening tests required confirmation testing by more specific alternate methods.

Additionally, the investigation found that DOCCS was one of only seven known state correctional systems in the country that disciplines incarcerated individuals based solely on the results of preliminary drug screening tests and without confirming results by a more specific alternative testing method.⁹ Most state correctional agencies in the United States either contract

⁸ These include an over-the-counter antacid and a natural sweetener used as a sugar substitute.

⁹ This review found that 35 states have policies addressing confirmation testing, seven states did not require confirmation testing prior to disciplinary action, and the drug testing policies for the remaining eight states was not determined.

for confirmatory testing services with private laboratories or conduct confirmatory testing using state-run laboratories.

Notably, prior to referring this complaint to the Inspector General, DOCCS, on August 19, 2019, ceased testing the urine of incarcerated individuals for buprenorphine. DOCCS later reversed the punishments of those individuals found guilty, which included releasing 140 incarcerated individuals from internal confinement and reversing and expunging their records.¹⁰

On November 5, 2019, after the Inspector General's then ongoing investigation found additional deficiencies in DOCCS' Incarcerated Individual Drug Testing Program for other prohibited substances, the Inspector General formally advised DOCCS that it immediately cease taking adverse action against incarcerated individuals based on positive drug test results using Microgenics systems for all illegal drugs without first confirming those results by a more specific alternative method. DOCCS immediately accepted this recommendation and in December 2019, began using an outside laboratory to confirm all positive results of drug screening tests prior to taking administrative action.

On December 31, 2019, after the Inspector General found similar flaws in DOCCS' testing for synthetic cannabinoids, the Inspector General formally advised DOCCS to reverse the disciplinary dispositions and expunge the records of those individuals who tested positive for synthetic cannabinoids. DOCCS also complied with these recommendations.

On January 15, 2020, DOCCS terminated its contract with Microgenics.

On February 22, 2021, DOCCS resumed its Incarcerated Individual Drug Testing Program after acquiring another drug testing vendor. DOCCS also revised its Urinalysis Testing Policy to require that "all initial positive test results will be sent to the outside laboratory for confirmation testing." DOCCS now uses a preliminary drug screening test known as the Premier Biotech Bio-Cup to analyze urine samples from incarcerated individuals. Positive results from these preliminary screening tests are then tested using a more specific alternative method: gas chromatography – mass spectrometry (GC-MS) and/or liquid chromatography – tandem mass spectrometry (LC-MS/MS), by Cordant Health Solutions.

In light of the termination of the Microgenics contract and the restructuring of the Incarcerated Individual Drug Testing Program, the Inspector General recommends that DOCCS

¹⁰ These incarcerated individuals were released between September 11 and October 22, 2019.

review its policies to ensure that DOCCS medical and legal staff review and approve any future modifications to the program. DOCCS must also ensure that when incarcerated individuals test positive for illegal drug use, its medical staff reviews any drugs prescribed by the New York State Office of Mental Health to those incarcerated individuals for treatment.

Additionally, the Inspector General recommends that DOCCS undertake a review of its Contract Procurement Unit processes to ensure compliance with State Finance Law in all procurements. DOCCS' Counsel's Office should review and approve all contracts and purchase orders over a designated monetary threshold set by the agency after an internal review is conducted.

The Inspector General also recommends that DOCCS provide comprehensive training to its drug testing and hearing officers on the drug testing policy, tests, and instruments used in the program. In addition, testing and hearing officers should be reminded of the requirement to enter all required drug testing information into DOCCS' disciplinary tracking database and to consistently consult medical staff on possible cross-reacting drugs.

INTRODUCTION AND COMPLAINT

In 2017, the United States Department of Health and Human Services declared a public health emergency in response to the nationwide opioid crisis.¹¹ New York State found itself in the throes of this epidemic and continues to battle increased use of opioids and other drugs statewide.¹²

In support of its mission, DOCCS prohibits illegal drug use by individuals incarcerated in State prisons.¹³ DOCCS attempts to combat substance abuse in its correctional facilities through its alcohol and substance abuse treatment programs and the Incarcerated Individual Drug Testing Program.¹⁴

¹¹ <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>.

¹² https://www.health.ny.gov/community/opioid_epidemic/.

¹³ <https://www.ny.gov/agencies/departments-corrections-and-community-supervision>.

¹⁴ DOCCS operates the Alcohol and Substance Abuse (ASAT) and Comprehensive Alcohol and Substance Abuse (CASAT) programs. The former is available to all incarcerated individuals while the latter is available to certain incarcerated individuals approved for Presumptive Work Release. According to DOCCS' website, CASAT is "legislatively mandated substance abuse treatment developed to ensure that substance use disordered individuals receive the maximum benefit from a substance abuse treatment experience during their preparation for transition back to the community." Under CASAT, certain incarcerated individuals are provided a six-month intensive substance abuse treatment program followed by community reintegration (outpatient treatment) and aftercare (through Community Supervision).

On September 19, 2019, DOCCS informed the Inspector General that its newly acquired drug testing system, which tests incarcerated individuals' urine for the presence of various prohibited substances, may be producing inaccurate results. Specifically, DOCCS advised that drug tests at its facilities might falsely indicate a positive result when testing for the opioid buprenorphine. This drug testing system was procured by DOCCS from Microgenics and installed in DOCCS' facilities statewide beginning in January 2019.

Given the possible implications of faulty drug testing for incarcerated individuals, including unjustly prolonged prison sentences, extended confinement in cells, and loss of access to rehabilitation programs and privileges, the Inspector General immediately commenced a comprehensive investigation and ensured DOCCS suspended all buprenorphine drug testing and reversed all punishment resulting from positive buprenorphine tests. Additionally, during the investigation, when evidence indicated potential issues with other Microgenics' drug tests, the Inspector General likewise advised DOCCS to suspend these tests and reverse related adverse action against incarcerated individuals.¹⁵

DOCCS' Incarcerated Individual Drug Testing Program

Pursuant to DOCCS' Urinalysis Testing policy (Directive 4937), incarcerated individuals are given drug tests if suspected of illegal drug use, when involved in certain programs, and when randomly selected by an electronic program. Incarcerated individuals who participate in DOCCS' Family Reunion Program must submit up to three urine samples each visit of a family member (pre-visit, day of visit, and post-visit). Incarcerated individuals' samples are collected by DOCCS correction officers and tested by officers trained to conduct such tests.

Per policy, an incarcerated individual who fails two consecutive urine tests—an initial test and a “second test . . . performed on the same sample,” is issued a misbehavior report and immediately isolated.¹⁶ Subsequently, the incarcerated individual attends an administrative hearing at which they may respond to the allegations of drug use. Microgenics representatives may be contacted by telephone during these disciplinary hearings to respond to questions from incarcerated individuals about the drug testing process, tests, and instruments.

¹⁵ See attached November 5, 2019 and December 31, 2019 letters from the Inspector General to DOCCS acting Commissioner Annucci.

¹⁶ Directive 4937(IV)(G)(1)(d).

If found guilty at a disciplinary hearing, punishment includes isolation in SHU and cells (keeplock), and/or loss of “good-time,” family visitation rights, access to rehabilitation and work programs, the receipt of packages, and access to telephones and the commissary. Disciplined individuals may also miss scheduled parole interviews, thereby prolonging their incarceration. Further, disciplinary matters concerning drug use may adversely affect Board of Parole decisions and the granting of parole.

DOCCS Acquires a New Incarcerated Individual Drug Testing Vendor and Revises Its Drug Testing Policy

From at least 1999 to October 2018, DOCCS procured its urine drug tests and testing instruments for incarcerated individuals from Siemens Healthcare Diagnostics Inc. (Siemens).¹⁷ Under this contract, Siemens’ salesperson Brenda Collum was the company’s liaison with DOCCS from 1999 until 2015. In 2015, Collum left Siemens for employment at its competitor, Microgenics.

In 2011, then DOCCS Corrections Lieutenant Corey Bedard was assigned oversight of DOCCS’ Incarcerated Individual Drug Testing Program. In this role, Bedard worked closely with Collum on drug testing matters.

Also in 2011, Bedard discovered that DOCCS was paying Siemens more for its drug tests than the price Siemens offered to other agencies for these tests under a New York State centralized contract. When DOCCS’ contract with Siemens expired in 2013, Siemens agreed to provide to DOCCS drug tests at the lower prices found in the State centralized contract. However, Siemens then required that DOCCS lease its drug testing instruments, which had been previously provided to DOCCS without additional cost under the original contract.

In response, DOCCS required each of its then 52 correctional facilities to enter into separate, monthly lease agreements with Siemens for the drug testing instruments. This arrangement dramatically increased DOCCS’ statewide costs for the administration of its Incarcerated Individual Drug Testing Program.¹⁸ Consequently, in 2016, Bedard began a search for similar, lower-priced urine drug tests and instruments in order to cut costs.

¹⁷ Siemens Medical Solutions USA, Inc. d.b.a. Siemens Healthcare Diagnostics Inc.

¹⁸ In 2013, DOCCS and Siemens entered into a seven-year lease agreement for drug testing instruments at a cost of \$705 per testing instrument/ per month. At that time, with DOCCS operating 52 correctional facilities, the total cost for drug testing instruments under this lease was approximately \$440,000 per year. In addition, DOCCS purchased drug test kits from Siemens at an annual cost of approximately \$150,000.

In May 2016, Bedard recommended to his supervisors that DOCCS end its current instrument leases with Siemens and procure drug tests and instruments from another vendor. In July 2016, Bedard identified Microgenics as one potential new vendor and forwarded contact information for Collum, who was then a Microgenics salesperson, to his supervisors.

By November 2016, at Bedard's request, his supervisors approved a trial side-by-side comparison of Microgenics' and Siemens' drug tests and instruments at a correctional facility. In tests conducted in December 2016 and January 2017, both Microgenics' and Siemens' drug tests and instruments performed comparably, with one exception: in one instance, an incarcerated individual's urine sample, which was tested using both systems, produced both a positive (Microgenics) and negative (Siemens) result for the presence of the illegal drug buprenorphine.¹⁹

In January 2017, Microgenics advised DOCCS that the contradictory result found in the side-by-side comparison was due to its test. Specifically, Microgenics' CEDIA Buprenorphine Assay (Buprenorphine I test) had produced a false positive result for buprenorphine. According to Microgenics, this result was due to the fact that the incarcerated individual had likely consumed Tylenol with codeine, a medication he was prescribed, before providing a urine sample.

To overcome this failure with its test, Microgenics proposed to DOCCS that should DOCCS contract with Microgenics, Microgenics would provide DOCCS a new urine drug test that produced both fewer false positive and false negative test results than its Buprenorphine I test. This test, the CEDIA Buprenorphine II Assay (Buprenorphine II test), had not yet been approved for use by the United States Food and Drug Administration (FDA), which is the federal regulatory agency responsible for reviewing and approving such tests by government agencies and in the private sector.

In February 2017, DOCCS began its public search for a new provider of drug tests and instruments for its Incarcerated Individual Drug Testing Program by requesting information from interested companies. Bedard emailed Collum directly to inform her of the public notice and consequently, Microgenics began to prepare its bid.

¹⁹ Buprenorphine, sold under the trade names Buprenex, Suboxone, and Subutex, is a narcotic used in clinical settings to assist with the treatment of opiate addiction. It is also a controlled substance under New York Public Health Law, Schedules of Controlled Substances, §3306.

In 2017 and into mid-2018, DOCCS commenced a competitive procurement and solicited bids from companies for drug testing systems. Four companies submitted bids, including Siemens and Microgenics. In October 2018, DOCCS awarded Microgenics a five-year contract to provide drug tests and instruments for its Incarcerated Individual Drug Testing Program. As part of this contract, Microgenics made available its technical service representatives to provide statements at DOCCS' disciplinary hearings. The estimated value of this contract was \$1.6 million over the five-year period, an average annual cost of approximately \$320,000. Microgenics provided DOCCS several different drug tests under this contract, including the Buprenorphine II test and a test for synthetic cannabinoids known as the CEDIA AB-PINACA test (AB PINACA test), among others.



Microgenics' CEDIA Buprenorphine II test kit (ThermoFisher)

Prior to DOCCS' implementation of Microgenics' drug testing system, Bedard was tasked by DOCCS with revising its Urinalysis Testing policy.²⁰ This revision was necessary as

²⁰ Bedard's supervisors at this time were Donald Venettozzi, the director of Special Housing and Incarcerated Individual Disciplinary Programs, and Anthony Rodriguez, the assistant director. In January 2019, Bedard was promoted to another position and Jennifer Booth became the head of the program.

the policy at that time appended a description of the “principles and validity” of the drug testing program, which was based on a then 32-year-old court case that affirmed DOCCS’ testing procedures using Siemens’ drug testing systems. This 1985 federal class action lawsuit, *Peranzo et al. v. Coughlin, et al. (Peranzo)*, did not refer to Microgenics’ drug testing systems.²¹ Notably, Siemens’ and Microgenics’ analyses operate using different substances and methodologies.

In order to revise DOCCS’ drug testing policy, Bedard turned to Microgenics salesperson Collum. In November 2018, Collum provided Bedard excerpts from scientific journals which she indicated equated Siemens’ and Microgenics’ technologies and could be included in the new policy. Bedard revised DOCCS’ drug testing policy accordingly.

Between January and April 2019, Microgenics installed its drug testing systems at each of DOCCS’ then 52 correctional facilities. Also at this time, Microgenics provided DOCCS staff at each facility training on its urine drug tests and testing instruments, and confirmed the instruments were properly cleaned and calibrated and that DOCCS staff could do the same. Upon completion of the installation and training at each facility, drug testing of incarcerated individuals was resumed using Microgenics’ testing systems.

Incarcerated Individuals Allege Microgenics’ Drug Tests Produce False Positive Results

Upon DOCCS’ implementation of Microgenics’ drug testing systems in its facilities, complaints lodged by incarcerated individuals of false positive drug tests noticeably increased.²² Among the complaints received by DOCCS were those from individuals who had never before tested positive for drug use while incarcerated with DOCCS.

One such compelling claim came from a female incarcerated at Albion Correctional Facility. In several letters to DOCCS acting Commissioner Anthony Annucci, this individual, who had never before tested positive for drug use during her then more than two-year incarceration with DOCCS, asserted that a January 2019 drug test wrongly indicated that synthetic cannabinoids—“K2/Spice”—had been detected in her urine sample. As a consequence of this and a subsequent Microgenics drug test²³, the incarcerated individual was confined in

²¹ *Peranzo v. Coughlin*, 608 F. Supp. 1504 (S.D.N.Y. 1985).

²² Multiple DOCCS employees testified to the Inspector General that they had noticed an increase in complaints at their respective facilities since the implementation of Microgenics’ drug testing systems.

²³ The incarcerated individual again tested positive for synthetic cannabinoids in early March 2019, despite being confined to SHU as a punishment for the original drug use violation. Notably, incarcerated individuals confined in

keeplock (40 days) and SHU (45 days), lost her prison job and coveted housing assignment, and lost privileges including recreation time, receipt of packages, and telephone use for a total of 105 days. Most importantly to the individual, she lost the privilege to participate in DOCCS' Family Reunion Program and therefore was denied the continuation of visits with her three children.

In her February and March 2019 letters to the commissioner, this individual noted that while incarcerated at DOCCS she had sought rehabilitation by earning a high school diploma, completing Incarcerated Individual Program Associate training (where she assisted prison staff in new incarcerated individual orientation and GED preparation programs), and participating in the Medaille College program. In addition, she participated in DOCCS' Alcohol and Substance Abuse Treatment Program, where she served as a facilitator and "happily celebrated my second year of sobriety."

Although the individual noted that she was taking four prescribed drugs at the time she provided her urine samples, none appeared as cross-reacting substances in Microgenics' scientific literature—literature that she found "complicated and confusing." Despite forcefully asserting she had taken no illegal drugs, she wrote that "after testimony from pharmacy and the testing officer . . . it became clear that I was out of my element; and I believed the two witnesses that my test was performed properly."

In another example, a woman who upon her admission to DOCCS' Shock Incarceration Program at Lakeview Shock Incarceration Facility in August 2019 asserted that a drug test wrongly indicated that synthetic cannabinoids had been detected in her urine sample. Because of this and a subsequent Microgenics test, she lost privileges including visitation, recreation time, receipt of packages, and telephone use for a total of 30 days. Most notably, she was removed from the Shock program, which if she completed without incident would have made her likely eligible to be released within six months. Instead, she was not released until September 2020.

In yet another example, two incarcerated individuals at Attica Correctional Facility tested positive for drug use in February 2019. Both had served lengthy terms with DOCCS and never previously tested positive for drugs while incarcerated. The first individual, then incarcerated with DOCCS for almost a decade and a participant in DOCCS' Alcohol and Substance Abuse Treatment Program, tested positive for buprenorphine. The second individual,

SHU are individually confined in a secure cell 23 hours each day, and individually recreate one hour each day in enclosed and secure areas.

who was incarcerated since 1984 and participated in DOCCS' Family Reunion Program, tested positive for synthetic cannabinoids. Each incarcerated individual was issued a misbehavior report and confined to their respective cells pending a disciplinary hearing. Each contested their purported positive test results to DOCCS.²⁴

Attica Correctional Facility Responds to Incarcerated Individuals' Claims of False Positive Drug Test Results

In March 2019, in response to the many claims of false test results at Attica, a correction officer at the facility who suspected possible testing errors contacted Microgenics and requested a review of test results for 18 individuals who had recently tested positive for drug use at the facility. Attica executive staff notified incarcerated individuals that DOCCS was consulting with Microgenics to determine whether there were any issues with the drug tests or instruments. On March 4, 2019, a Microgenics field technician examined the positive test reports and found no errors.

As complaints of false positive drug test results continued to grow at Attica, in April 2019, the facility's Incarcerated Individual Liaison Committee (a representative group of incarcerated individuals selected by other incarcerated individuals to raise concerns with facility staff) requested that Attica discontinue its use of Microgenics' drug tests and instruments. In response, Attica staff advised the committee that although Microgenics had reviewed a number of recent positive drug test results at the facility and found no issues, Attica would request that a Microgenics field technician visit the facility and inspect its drug tests and instruments to ensure DOCCS was using proper procedures.

In May 2019, a Microgenics field technician visited Attica and advised the new head of DOCCS' Incarcerated Individual Drug Testing Program, Jennifer Booth, that he had found no errors with the drug tests, instruments, or procedures performed by the testing officers. Microgenics salesperson Collum opined to Booth that the increase in positive drug test results could be because the Buprenorphine II and synthetic cannabinoids tests were more sensitive than earlier tests. Booth informed her supervisors of Microgenics' responses.²⁵

²⁴ Subsequently, these misbehavior reports were dismissed and expunged from the incarcerated individuals' records due to technical errors; the individuals had not been offered an opportunity to consult with staff prior to their hearings, as is provided by DOCCS directive.

²⁵ Booth was supervised at this time by Venettozzi and Rodriguez. Subsequently, in July 2019, Charles Kelly, an associate commissioner and the executive assistant to acting Commissioner Annucci, began to assert some oversight over the Incarcerated Individual Drug Testing Program and Booth.

Prisoners' Legal Services of New York Files Complaints with DOCCS

In June 2019, DOCCS received a complaint from Prisoners' Legal Services of New York (PLSNY), a not-for-profit organization that provides legal representation and assistance to indigent incarcerated individuals.²⁶ The complaint contained allegations of false positive test results for buprenorphine and synthetic cannabinoids made by four individuals who were incarcerated at Albion, including the woman cited earlier in this report.

PLSNY's complaint noted that the four individuals had no prior history of drug use in prison or any prior disciplinary history and had "wholeheartedly applied their energies to rehabilitation." Additionally, the complaint emphasized that many of the tests were not random but were taken at times when the individuals were aware they would be screened and taken as a requirement of programs they were participating in, including the Family Reunion, Alcohol and Substance Abuse Treatment (ASAT), and college credit programs. One individual even submitted to a urine test in support of her application for participation in a DOCCS' work release program. According to PLSNY, these facts made it beyond improbable that these individuals "would each suddenly elect to take drugs . . . while participating in programs where they knew drug testing was a regular and known occurrence." PLSNY advised that these collective drug results indicated the urinalysis testing equipment at Albion was materially or operationally defective.

PLSNY followed up with a second letter to DOCCS a month later in July 2019, which stated that PLSNY and several other incarcerated individuals' rights organizations had received numerous additional complaints of false positive drug test results from individuals incarcerated at Albion, Attica, Bare Hill, Eastern, Fishkill, Great Meadow, and Green Haven correctional facilities.²⁷ PLSNY noted that given these widespread claims of false drug test results from individuals, many of whom had little or no prior history of substance abuse or drug-related misconduct, "it is highly likely the [Microgenics] drug testing apparatus, recently installed at many DOCCS facilities, has an operational or technical fault of some type."

PLSNY also advised DOCCS of the detrimental consequences of such false drug test results. According to PLSNY, many individuals reported they believed that medications prescribed to them to treat medical and mental health issues might be the cause of the false

²⁶ <https://www.plsny.org/about-pls.html>.

²⁷ The other incarcerated individuals' rights organizations included The Legal Aid Society Prisoners' Rights Project and the CUNY School of Law Defenders Clinic.

positive drug test results, and they had been forced to choose between continuing their medications or forgoing them in order to avoid disciplinary sanctions. PLSNY asked DOCCS to take immediate investigatory action to determine whether prescribed drug cross reactivity could be a factor in the surge in reports of false positive drug test results and concluded that if DOCCS took no action to address this matter, it would be “unnecessarily exposing incarcerated persons to undeserved punitive sanctions, which arbitrarily inflates their disciplinary record and impacts their ability to parole.”²⁸

Subsequently, in November 2019, PLSNY and a private law firm filed a federal class action lawsuit in the Eastern District of New York against Microgenics for those incarcerated individuals “unjustly punished for false positive drug test results.”²⁹ In September 2020, an incarcerated individual filed a lawsuit against Microgenics and DOCCS in the Eastern District of New York alleging the same.³⁰ With similar claims, in July 2021, an incarcerated individual filed a lawsuit in the Southern District of New York.³¹ These lawsuits are currently pending.

DOCCS Reviews Claims of False Positive Drug Test Results

In July 2019, as complaints of false positive test results continued to mount, Booth, the head of DOCCS’ Incarcerated Individual Drug Testing Program, arranged a meeting to discuss the matter with Microgenics salesperson Collum and Collum’s supervisor, Larry Wilkie. At this meeting, Collum and Wilkie requested DOCCS provide urine samples from incarcerated individuals who had tested positive for buprenorphine and a list of medications taken by these specific individuals so that any potential cross reactivity with the medications could be examined.

Later that same month, after Booth had gathered urine samples from six individuals who tested positive for buprenorphine at Eastern Correctional Facility and a list of all medications used by these specific individuals, a Microgenics field technician visited the facility and retested the urine samples using Microgenics’ drug tests and instruments. All again returned positive test

²⁸ In September 2019, after not receiving a response from DOCCS, PLSNY again wrote DOCCS of the numerous additional complaints of false positive drug test results it had received from incarcerated individuals incarcerated at Eastern, Fishkill, Attica, Albion, Collins, Sing, and Woodbourne correctional facilities. In this letter, PLSNY advised DOCCS it “must deal with the issue of unreliable drug testing immediately” or PLSNY would be forced to take appropriate action.

²⁹ See, *Steele-Warrick v. Microgenics Corporation*, U.S.D.C. (E.D.N.Y.), Case No. 1:19-cv-06558.

³⁰ See, *Wills v. Microgenics Corporation and DOCCS*, U.S.D.C. (E.D.N.Y.), Case No. 1:20-cv-04432.

³¹ See, *Taylor v. Microgenics Corporation and DOCCS*, U.S.D.C. (S.D.N.Y.), Case No. 7:21-cv-06452.

results. As for the promised review of possible cross reactivity with medications, no results were ever reported by Microgenics to DOCCS.

In late July 2019, Charles Kelly, then an associate commissioner and Annucci's executive assistant, began a broader review of incarcerated individuals' claims of false positive drug test results. At his direction, in August 2019, DOCCS provided Microgenics with urine samples from another group of six incarcerated individuals who had tested positive for buprenorphine. Microgenics agreed to have these urine samples tested using analyses performed on more specific testing instruments.

Microgenics provided half of each urine sample to two different laboratories for confirmatory testing. The first laboratory found that four of the urine samples had no buprenorphine, and the second laboratory found that two of those urine samples had no detectable buprenorphine and the other two had trace amounts of buprenorphine at levels below positive test results. In sum, the outside laboratories had found that four of the six urine samples had returned false positives to DOCCS. Despite this disturbing outcome, Microgenics did not inform DOCCS of these results at this time or subsequently. Nor did Kelly follow up with Microgenics about the results of the retesting of the six urine samples.

Separately, in August 2019, Kelly provided an outside company urine samples from yet another group of six individuals who had tested positive for buprenorphine at Eastern Correctional Facility. The outside company, which used more specific instruments and processes to provide confirmatory testing services to DOCCS for parolees under an established contract, found that five of the six urine samples contained no detectable buprenorphine. Once again, using Microgenics' tests and instruments, DOCCS had received false positive results when testing urine samples from incarcerated individuals.

DOCCS Suspends Buprenorphine Testing, Reverses Sanctions, and Alerts the Inspector General

On August 19, 2019, DOCCS issued a memorandum to all State correctional facility superintendents instructing them to continue to obtain urine samples from those suspected of drug violations or randomly chosen but to cease taking any disciplinary action for positive buprenorphine tests. At this time, DOCCS did not address those incarcerated individuals then being punished for positive buprenorphine test results.

On September 4, 2019, DOCCS and Microgenics participated in a conference call to discuss the allegations of false positive drug tests due to cross reactivity with medications taken by incarcerated individuals. On that same day, Microgenics received results from one of the two outside laboratories, which confirmed that four urine samples from incarcerated individuals did not contain buprenorphine. Rather than share this information with DOCCS, Microgenics instead recommended that DOCCS transition from using the Buprenorphine II test to the less sensitive Buprenorphine I test.

More than three weeks after issuing the memorandum, on September 10, 2019, DOCCS directed its correctional facility superintendents to end the punishment of individuals then serving internal confinement and/or other restrictions as a result of receiving a positive buprenorphine test result. During the next five weeks, DOCCS reviewed the disciplinary records of incarcerated individuals, including those transferred to other facilities during the relevant period, ultimately releasing 140 individuals from internal confinement. DOCCS also began to reverse and expunge incarcerated individuals' records of associated misbehavior reports.

The New York State Attorney General Files a Civil Lawsuit on Behalf of DOCCS Against Microgenics

In February 2020, the New York State Attorney General filed a civil lawsuit on behalf of DOCCS against Microgenics in Albany County Supreme Court with eight causes of action including breach of contract and negligent misrepresentation. The lawsuit is currently pending.

DOCCS DISCIPLINED INCARCERATED INDIVIDUALS BASED ON THE RESULTS OF PRELIMINARY AND UNCONFIRMED DRUG SCREENING TESTS

The Inspector General's investigation found that DOCCS disciplined individuals based on the results of Microgenics' preliminary drug screening tests and ignored test instructions that results be confirmed using a more specific alternative method. DOCCS also unreasonably relied on three-decade old case law—in which the court's holdings were based on a different manufacturer's drug test—to justify forgoing the confirmation of Microgenics' preliminary drug screening test results. Specifically, the court in *Peranzo* did not consider cross-reacting substances possibly found in incarcerated individuals' urine samples, further calling into question DOCCS' reliance on this case to abstain from confirmatory testing. These deficiencies worked to the detriment of incarcerated individuals who were disciplined, confined, and lost privileges based on drug test results that were or may have been in error.

DOCCS Failed to Confirm Preliminary Drug Screening Test Results Using a “More Specific Alternative” Method

Pursuant to DOCCS’ Urinalysis Testing policy, incarcerated individuals’ urine samples are analyzed by trained correctional officers using drug testing instruments. If a test produces a positive result, the policy requires that “a second test shall be performed on the same sample.” If this second test also produces a positive result, the incarcerated individual is issued a Misbehavior Report and the positive test result “may be used as evidence of the illicit use” of a prohibited drug by the incarcerated individual in a subsequent disciplinary hearing.

In practice however, during the period at issue, DOCCS initially tested an individual’s urine sample using Microgenics’ tests and instruments located in each facility.³² When a test produced a positive result, DOCCS then merely retested that urine sample using the same Microgenics test, instrument, and method.³³ This second retest was contrary to instructions provided with Microgenics test kits, which require confirmatory testing using a “more specific *alternative*” method. (Emphasis added).

Confirmatory Testing of Preliminary Drug Screening Results

Microgenics manufactures drug tests used by DOCCS, including the Buprenorphine II and AB-PINACA (synthetic cannabinoids) tests, among others. The tests are sold with package inserts containing written instructions describing the tests’ intended use, test procedures and guidelines, reagent and sample handling, and test limitations, and include lists of substances that Microgenics has tested for cross-reactivity.

For example, the first four paragraphs of the package insert for the Buprenorphine test include the following language:

The assay is intended to be used in laboratories and provides a simple and rapid analytical screening procedure to detect buprenorphine and its metabolites in human urine.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method.

Clinical and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary results are used.

³² These instruments were known as Microgenics Indiko Plus Benchtop Analyzers.

³³ In interviews with the Inspector General, DOCCS personnel consistently and incorrectly referred to this second test as a “confirmatory test.”

Thermo
SCIENTIFIC

CEDIA® Buprenorphine II Assay

[FVO] For In Vitro Diagnostic Use Only

Rx Only

REF: 1002043 (1 x 17 mL KIT)
1002050 (65 mL KIT)

Intended Use

The CEDIA® Buprenorphine II Assay is a homogeneous enzyme immunoassay for the qualitative and/or semi-quantitative determination for the presence of buprenorphine and its metabolites in human urine at a cut-off concentration of 10 ng/mL. The assay is intended to be used in laboratories and provides a simple and rapid analytical screening procedure to detect buprenorphine and its metabolites in human urine. The assay is designed for use with a number of clinical chemistry analyzers.

The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method!

Clinical and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary results are used. For In Vitro Diagnostic Use Only.

Summary and Explanation of the Test

Buprenorphine is a semi-synthetic opioid. Buprenorphine is a strong analgesic. Buprenorphine has been administered sublingually as an analgesic used in Europe and in the United States for the treatment of moderate to severe pain. The FDA has approved the use of buprenorphine as an active drug for the treatment of the opioid dependence. It has also been shown to be effective in the treatment of pain with intravenously injected buprenorphine, such as buprenorphine-3-buprenorphine and by buprenorphine-guacacate.

The CEDIA Buprenorphine II unique homogeneous enzyme immunoassay uses a β -galactosidase enzyme-linked buprenorphine fragments. These fragments, in the assay format, cleave the substrate chromogenic substrate, 4-nitrophenol, to produce a color change at 410 nm.

In this assay, the substrate is the buprenorphine fragment of the enzyme present in the sample. The enzyme, in the presence of the substrate, will cleave the substrate to form active analyte. If the analyte competing on the β -galactosidase fragments, and formed and resultant absorbance present in the sample.

Reagents

- EA Reconstitutes Buffer**
Contains buffer salts, 0.5% SA - 1.0 mg/L, stabilizer.
- EA Reagent**
Contains 0.171 g/L Enzyme Adjuvant buffer salts and preservatives.
- ED Reconstitutes Buffer**
Contains buffer salts, stabilizer, and preservatives.
- ED Reagent**
Contains 0.175 mg/L Enzyme Dator conjugated to buprenorphine derivative, 1.87 g/L chromogenic reagent β -D-galactosidase, stabilizer, enzyme and preservatives.

Additional Materials Required (sold separately):

REF	Kit Description
10021290	CEDIA Negative Calibrator (1 x 7.5 mL)
10021291	CEDIA Buprenorphine II Calibrator 10 ng/mL (1 x 5 mL)
10020800	CEDIA Buprenorphine II Calibrator 20 ng/mL (1 x 5 mL)
10020801	CEDIA Buprenorphine II Calibrator 50 ng/mL (1 x 5 mL)
10020802	CEDIA Buprenorphine II Calibrator 100 ng/mL (1 x 5 mL)
10020804	CEDIA Buprenorphine II Low (7.5 ng/mL) and High (12.5 ng/mL) Controls (2 x 5 mL each)

Intended Use

The CEDIA® Buprenorphine II Assay is a homogeneous enzyme immunoassay for the qualitative and/or semi-quantitative determination for the presence of buprenorphine and its metabolites in human urine at a cut-off concentration of 10 ng/mL. The assay is intended to be used in laboratories and provides a simple and rapid analytical screening procedure to detect buprenorphine and its metabolites in human urine. The assay is designed for use with a number of clinical chemistry analyzers.

The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method!

Clinical and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary results are used. For In Vitro Diagnostic Use Only.

Warnings and Precautions

DANGER: Powder reagents contain 45% w/w Bovine Serum Albumin (BSA) fragments and <1% w/w Sodium Azide. Liquid reagents contain 4.5% Bovine Serum, 4.5% Sodium Azide, and 0.1% Drug-Specific Antibody (Mouse).

The reagents are harmful if swallowed.

H317 - May cause allergic skin reaction.
H373 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
EUH022 - Contact with acids liberates very toxic gas.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. If inhaled: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or a doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container in accordance with local/regional/national/international regulations.

In the case of accidental spill, clean and dispose of material according to your laboratory's Standard Operating Procedure (SOP), local, and state regulations.

CAUTION: Do not use reagents if the expiration date of the analyzer before performing the assay. Refer to the analyzer specific application sheet for additional information.

Store reagents at 2-8°C. **DO NOT FREEZE.**

For shelf life of the unopened components, refer to the box or bottle labels for the expiration date.

RT Sealbox: 30 days refrigerated on analyzer or at 2-8°C.
4°C Sealbox: 90 days refrigerated on analyzer or at 2-8°C.

Importantly, the test instructions note that the test is a “screening procedure” that provides “only a preliminary analytical test result.” Further, the instructions state that a “more specific alternative chemical method *must* be used to obtain a confirmed analytical result.” (Emphasis added.) The instructions for Microgenics’ synthetic cannabinoid test read similarly.

The “preferred” confirmatory methods per the Microgenics’ test instructions include gas chromatography – mass spectrometry (GC/MS) and liquid chromatography – tandem mass spectrometry (LC-MS/MS). These confirmatory tests, which are usually performed by outside laboratories, precisely identify and quantify the presence of drugs in urine samples. The confirmatory tests act to eliminate any false positive preliminary drug screening test results, which may be caused by a faulty test, procedure, or cross-reacting substance, among other factors.

However, despite Microgenics' instructions, the Inspector General's investigation found that DOCCS failed to conduct confirmatory testing for incarcerated individuals' urine samples that tested positive when screened. During the period Microgenics' drug testing kits were used by DOCCS, 3,018 incarcerated individuals tested positive for a prohibited substance.³⁴

Of significant note, the Inspector General learned that DOCCS' Community Supervision division, which oversees its parolee drug screening program, has for more than two decades used an outside laboratory for GC/MS confirmatory testing for parolee drug screening tests.³⁵ Community Supervision only takes action against a parolee when a screening test is confirmed positive using this more specific alternate method.³⁶ However, the Corrections division of DOCCS did not adequately coordinate with the Community Supervision division to leverage the use of existing resources, which would have allowed for using the same vendor to cut costs and streamline processes. Additionally, Community Supervision could have provided guidance to Corrections about the importance of confirmatory testing from a lessons-learned perspective. This lack of collaboration within the agency not only presented missed opportunities, but contributed to the administration of inconsistent testing and undeserved punishments.

DOCCS Unreasonably Relied on Case Law as the Basis to Forgo Confirmatory Testing

According to the testimony of DOCCS witnesses, and as reflected in DOCCS' policy, the decision to forgo confirmatory testing of positive drug screening tests was made by DOCCS more than three decades ago pursuant to specific case law. The Inspector General's investigation found this court decision and DOCCS' drug testing policy were not appropriately reconsidered before or after DOCCS implemented Microgenics' drug testing systems in January 2019.

DOCCS' Urinalysis Testing policy includes an attachment entitled Enzyme Immunoassay Case Law, which describes "the scientific principles and validity of the testing apparatus." It cites federal case law in support of DOCCS' decision to forgo confirming positive preliminary drug test results using a more specific alternative method. The attachment reads:

In its decision dated October 26, 1987, in the federal class action suit of Peranzo et al. v. Coughlin, et al.,³⁷ the Southern District of New York found that 'with a

³⁴ DOCCS conducted drug tests of 24,228 incarcerated individuals during this period.

³⁵ DOCCS' Community Supervision unit uses a different manufacturer's drug screening test. Like Microgenics' tests, these screening tests also require confirmatory testing.

³⁶ Parolees who admit to drug use after a positive screening test may be charged with drug violations without the need for confirmatory testing.

³⁷ *Peranzo v Coughlin*, 675 F. Supp. 102 (S.D.N.Y. 1987).

98+% rate of accuracy, the double EMIT³⁸ testing as performed by DOCCS is sufficiently reliable so that the use of the results as evidence, even as the only evidence, in a disciplinary hearing does not offend due process.’ The Court relied upon DOCCS’ record of 98.7% accuracy rate in proficiency testing with the American Association of Bioanalysts over the past four years.

In *Peranzo*, State incarcerated individuals brought a class action lawsuit in 1985 against DOCCS and the Board of Parole³⁹ (Parole) claiming that the individuals’ 14th Amendment due process rights were violated when DOCCS and Parole punished them based on positive results from unreliable urine drug screening tests. Specifically, the individuals argued that DOCCS and Parole took disciplinary action against and denied parole for those accused of prohibited drug use after two positive screening tests. At this time, DOCCS used Siemens’ EMIT tests and instruments in its Incarcerated Individual Drug Testing Program to screen for marijuana and other prohibited drugs. Notably, no tests were available at this time for either buprenorphine or synthetic cannabinoids. The court in *Peranzo* found that DOCCS’ practice of twice using Siemens’ screening tests to test urine samples was reliable enough to satisfy due process concerns and ultimately granted DOCCS’ motion for summary judgment, dismissing the incarcerated individuals’ lawsuit.

The Inspector General’s investigation, however, found that DOCCS failed to perform an appropriate legal review to determine if the holding in *Peranzo*, which involved the use of Siemens’ drug testing systems in the 1980’s, remained a basis upon which to forgo confirmatory testing using Microgenics’ drug testing systems. Instead, with guidance provided only by Microgenics salesperson Collum, Bedard revised DOCCS’ drug testing policy, thereby giving equal deference to Siemens’ and Microgenics’ drug tests for composition, procedure, and reliability. Notably, Siemens’ and Microgenics’ analyses operate using different substances and methodologies.

Specifically, the investigation found that in October 2018, Bedard, then the administrator of DOCCS’ Incarcerated Individual Drug Testing Program, sought assistance from Microgenics salesperson Collum to revise DOCCS’ drug testing policy. Collum provided Bedard excerpts from scientific journals, which she indicated equated Siemens’ and Microgenics’ technologies and the reliability of the two testing systems. By considering the two technologies equal, the

³⁸ Siemens’ Enzyme Multiplied Immunoassay Technique (EMIT) tests.

³⁹ At this time, the Board of Parole was part of the Division of Parole. In 2011, the Division of Parole merged with the Department of Corrections to become the Department of Corrections and Community Supervision. Community supervision is generally referred to as parole.

holding in *Peranzo* would appear to support DOCCS' testing procedures using Microgenics' drug tests and instruments. This legal application of *Peranzo* allowed DOCCS to rely on Microgenics' preliminary drug screening tests as the sole basis for the discipline of incarcerated individuals, much as it had historically with Siemens' tests.

Notably, the investigation found that neither Bedard nor Collum had the requisite experience and education to evaluate the two technologies and ensure that the court's holding in *Peranzo* still legally applied. Additionally, Bedard did not seek an independent scientific review of his policy changes or provide the proposed policy to the DOCCS' chief medical officer for his evaluation. The Inspector General also found no evidence that DOCCS' Counsel's Office conducted a substantive review to ensure there was a sound basis for its continued reliance on *Peranzo*. Given the at least 44 false positive test results found by outside laboratories, the continued reliance on *Peranzo* was undoubtedly misplaced.

The Court in *Peranzo* Did Not Consider Cross-Reacting Substances Possibly Found in Actual Urine Samples

The court in *Peranzo* did not consider the possible presence of cross-reacting substances in urine samples provided by incarcerated individuals for drug tests. This fact makes DOCCS' reliance on *Peranzo* to forgo confirmatory testing questionable.

The *Peranzo* decision emphasized DOCCS' "record of 98.7% accuracy rate in proficiency testing" when holding that DOCCS' practice of twice using Siemens' screening test to test urine samples was reliable enough to satisfy due process concerns. However, the Inspector General's investigation found that DOCCS' proficiency testing was not conducted with actual urine samples but instead with samples of a solution that either contained or did not contain a target drug. Notably, these samples were free of any possible cross-reacting substances. Moreover, Siemens' instruments, procedures, and tests were used rather than Microgenics' instruments, procedures, and tests. DOCCS provided no evidence to the Inspector General of having obtained proficiency testing results using actual urines samples and Microgenics' instruments, procedures, and tests.

Microgenics evaluates its drug tests by determining if certain substances cross react to produce false positives.⁴⁰ Its drug tests are provided with documentation reflecting substances tested, cross reactions observed, and the quantities of the substances present in the samples at

⁴⁰ See Addendum 3, which illustrates the manner in which the tests produce results.

which cross reactions were either observed or not observed. Instructions provided with drug test kits note that substances other than those investigated by Microgenics “may interfere with the test and cause false results.” Significantly, the investigation found that Microgenics did not publish test results for certain substances found in over-the-counter drugs and medications commonly prescribed to and used by incarcerated individuals.

As a consequence of early reports of false positive results by outside laboratories conducting confirmatory testing, DOCCS began using an outside laboratory for confirmatory testing of all positive preliminary drug screening test results in November 2019. In the five months that followed, more than 27 percent of all positive Microgenics preliminary screening tests submitted by DOCCS to this outside laboratory were found to be in error—false positives.⁴¹ It remains unknown if the cause of any of these false positive test results is due to cross-reacting substances.

These results call into question the reliability of Microgenics’ drug testing systems for the incarcerated individual population, make imperative the confirmation of positive preliminary drug screening test results, and make DOCCS’ reliance on *Peranzo* inapposite.

DOCCS FAILED TO TAKE PROMPT CORRECTIVE ACTION AFTER DISCOVERING FALSE POSITIVE DRUG TEST RESULTS

The Inspector General found that Charles Kelly, then DOCCS associate commissioner and executive assistant to the acting commissioner, failed to take prompt corrective action after discovering in August 2019 that five incarcerated individuals who tested positive for buprenorphine using Microgenics’ drug testing systems had no detectable buprenorphine in their urine.

In June 2019, Kelly commenced a review of incarcerated individuals’ allegations of false positive drug urine tests after facilities began “receiving a lot of positive results with [incarcerated individuals] that had no drug history and some superintendents were concerned.”

⁴¹ The Inspector General’s review of confirmation testing by outside laboratories of urine samples was greatly hindered by DOCCS’ failure to maintain complete records of confirmation test results and sufficiently identify samples sent for testing. Between November 2019 and March 2020, DOCCS submitted at least 158 positive preliminary/screening tests to an outside laboratory for review. Of this number, 18 samples were rejected for various reasons. Of the 140 remaining tests, 39 returned false positive results. These included 25 synthetic cannabinoid tests, 12 THC tests, and two opiate tests. The Inspector General also identified another 175 tests of urine samples that were conducted by this outside laboratory but not included in DOCCS’ database. Additionally, the Inspector General found that DOCCS may have neglected to record thousands of other testing results in its drug testing database.

According to Kelly, he “reported it up . . . [and] it became my problem.” Kelly, whose job duties included assisting the commissioner with special projects and drafting agency policies, had no direct oversight of DOCCS’ Incarcerated Individual Drug Testing Program, or education, training, or experience in drug testing. Kelly enlisted Bedard, the former administrator of the program, and Booth, the current administrator, in his review of the matter.

As part of his review, in August 2019, Kelly and Bedard consulted with Timothy O’Brien, the DOCCS director of internal operations for community supervision, to learn about the State’s parolee drug testing program. O’Brien advised that the parolee drug testing program did not use the Microgenics’ tests used by DOCCS for State incarcerated individuals but instead another manufacturer’s preliminary drug screening tests for parolees.⁴² O’Brien further advised that in the event a parolee’s urine sample produces a positive test result and the parolee does not admit to consuming drugs, the sample is sent to an outside laboratory for confirmatory testing using GC/MS.⁴³ Significantly, O’Brien advised Kelly and Bedard that only if a preliminary drug screening test is confirmed positive using this more specific alternative method does Community Supervision take action against a parolee. Despite learning that Community Supervision, a DOCCS division, obtained confirmatory testing for all positive preliminary drug screening test results (absent a parolee’s admission of guilt), Kelly took no action at this time to review and revise the Incarcerated Individual Drug Testing Program’s procedures.

In mid-August 2019, at Kelly’s direction, DOCCS provided Microgenics with urine samples from six incarcerated individuals who had tested positive for buprenorphine. Microgenics provided one half of each urine sample to a Massachusetts-based laboratory and the second half to a Germany laboratory. Each laboratory, using more specific instruments and processes, tested the identical samples for buprenorphine. The Massachusetts laboratory found that four of the urine samples had no buprenorphine. The German laboratory found that two of those urine samples had no detectable buprenorphine and the other two had trace amounts of buprenorphine at levels below positive test results. In sum, the outside laboratories had found that four of the six urine samples had returned false positives to DOCCS. Despite this alarming finding, Microgenics never informed DOCCS of these results.

⁴² Community Supervision (commonly known as Parole) uses iCup urinalysis tests manufactured by Abbott Laboratories.

⁴³ Parolees who admit to drug use after a positive screening test may be charged with drug violations.

On August 9, 2019, Kelly directed that another six urine samples that had tested positive for buprenorphine at Eastern Correctional Facility using Microgenics' preliminary drug screening tests be sent to an outside laboratory for confirmatory testing.⁴⁴ On August 12, 2019, the outside laboratory, using more specific alternative methods, advised Kelly that it had found that five of the six samples did not contain buprenorphine.⁴⁵

Kelly, who testified that he was aware at this time that the five individuals who provided the urine samples at Eastern Correctional Facility were still in confinement pending sentencing on their disciplinary charges, took no immediate remedial action to address the matter. When asked by the Inspector General whether the results from the outside laboratory provided evidence that the individuals may not be guilty, Kelly responded, "Possibly." According to Kelly, based on articles he had read, he believed the findings of the outside laboratory were unreliable because the samples had "degraded." Kelly provided no scientific evidence to the Inspector General to support his contention. Kelly also testified that he may have verbally advised his superiors of the outside laboratory's findings, but he did not provide them with the actual test results.

Kelly should have immediately sought to reverse the disciplinary decisions and expunge the records of the five Eastern Correctional Facility incarcerated individuals who had tested positive for buprenorphine using Microgenics' preliminary drug screening tests but who were determined by an outside laboratory to have no detectable buprenorphine in their urine samples. Additionally, this discovery should have caused Kelly to immediately notify acting Commissioner Annucci and other DOCCS executives about these irregularities with Corrections' drug testing program.

DOCCS LIKELY IMPROPERLY PROCURED ITS DRUG TESTING SYSTEMS AND SERVICES

The Inspector General's investigation found that DOCCS appeared to violate New York State Finance Law when contracting for commodities and services for its Incarcerated Individual Drug Testing Program.

State Finance Law section 163 requires that State agencies give first priority to preferred sources when the commodities or services sought are available from a preferred source in the

⁴⁴ Kelly testified that he may have informed acting Commissioner Annucci and Deputy Commissioner James O'Gorman that the samples were undergoing confirmatory testing.

⁴⁵ The samples analyzed by the outside laboratory were found to have no buprenorphine at or above the 1ng/ml cut-off value established for the test.

“form, function and utility” required by a State agency.⁴⁶ The New York State Office of General Services maintains a list of New York State Procurement Council-approved preferred source commodities and services.⁴⁷ If a preferred source does not meet the “form, function, and utility” requirement or cannot otherwise fulfill an agency’s request, an agency must next determine whether the commodities or services sought can be acquired through an OGS centralized contract, agency or multi-agency centralized contract, respectively. If not, an agency may procure commodities or services through competitive bidding.

However, the Inspector General’s investigation found that prior to 2014, DOCCS neglected to determine if drug testing kits for its Incarcerated Individual Drug Testing Program were available through a preferred source, OGS centralized contract, or agency or multi-agency centralized contract. Instead, DOCCS procured urine drug testing kits from Siemens at a higher price than prices listed in a New York State centralized contract. In 2014, also in apparent violation of State Finance Law, DOCCS entered into separate lease agreements for Siemens’ urine analyzers at each of its correctional facilities at a cost to DOCCS of approximately \$440,000 annually.

By way of background, in 2013, Bedard was assigned to oversee the Incarcerated Individual Drug Testing Program. At this time, DOCCS was utilizing urinalysis tests and instruments procured from Siemens. As part of its contract with DOCCS, Siemens provided its instruments at no cost but charged DOCCS for its urinalysis test kits, which included reagents, controls, and calibrators.

Bedard soon discovered that DOCCS was paying more for Siemens’ test kits than the price Siemens had agreed to provide State agencies in a New York State centralized contract. According to Bedard, when he informed DOCCS’ Budget Office, the office advised such an arrangement violated State Finance Law and the Siemens contract would be reviewed. Subsequent to this review, DOCCS demanded that Siemens provide it drug test kits at the lower price found in the centralized contract.⁴⁸ In response, Siemens advised it would instead charge for the use of its drug testing instruments.

⁴⁶ New York State Office of General Services, “NYS Procurement Bulletin: Preferred Source Guidelines,” <https://ogs.ny.gov/procurement/nys-procurement-bulletin-preferred-source-guidelines> (last accessed 10/22/2021).

⁴⁷ New York State Office of General Services, List of Preferred Source Offerings, Revised May 2020, https://ogs.ny.gov/system/files/documents/2020/05/the-list-of-preferred-source-offerings_0.pdf (last accessed 10/22/2021).

⁴⁸ The Inspector General was unable to confirm if DOCCS’ Budget Office conducted any such review.

In 2014, DOCCS and Siemens reached a fiscal agreement on the matter. As part and parcel of this agreement, Siemens would provide its drug test kits to DOCCS at the lower centralized contract price, and each DOCCS correctional facility would lease drug testing instruments from Siemens. As a result, DOCCS' costs to administer the Incarcerated Individual Drug Testing Program dramatically increased.⁴⁹

However, the investigation revealed that this agreement was entered into without following the mandates of State Finance Law. DOCCS failed to determine if urinalysis testing kits and instruments were available from a preferred source, State centralized contract, or agency or multi-agency centralized contract before entering into this new agreement with Siemens. In fact, representatives from DOCCS' Contract Procurement Unit advised the Inspector General that they had never performed such a procurement review when purchasing instruments and tests for DOCCS' Incarcerated Individual Drug Testing Program. Notably, DOCCS has procured drug tests for its Community Supervision parolee program using a State centralized contract for many years and did not explore using this existing vendor as a proposed approach.

In 2018, when DOCCS sought to acquire new drug testing systems, it again likely failed to follow the requirements of State Finance Law. Again, DOCCS did not determine if urinalysis testing kits and instruments were available from a preferred source, State centralized contract, or agency or multi-agency centralized contract. Instead, DOCCS initiated a competitive procurement without performing a diligent review.

DOCCS Failed to Perform Due Diligence in Procuring Microgenics' Drug Testing Systems

The Inspector General's investigation found that DOCCS failed to perform due diligence prior to contracting with Microgenics as DOCCS failed to understand that the company's preliminary drug screening tests alone do not produce reliable results and all positive results must be confirmed by a more specific alternative method when used in a correctional facility setting.⁵⁰

Specifically, the investigation found that Bedard, the administrator of DOCCS' Incarcerated Individual Drug Testing Program from 2011 to January 2019, coordinated

⁴⁹ According to Bedard, the costs almost doubled. From testimony and a review of records, DOCCS' total annual cost for drug testing systems under Siemens at this time was approximately \$590,000 while Microgenics drug testing systems cost DOCCS approximately \$320,000 annually.

⁵⁰ The use of such preliminary screening drug tests may be appropriate in a clinical setting and should be distinguished from use in a correctional/penal setting.

procurement of Microgenics' drug testing systems and perpetuated DOCCS' misinformed practice of relying solely upon positive results of preliminary drug screening tests to discipline incarcerated individuals. Bedard, who was responsible for ensuring drug tests were administered properly, tracking test results, and training hearing officers, requested that DOCCS reevaluate its urine testing vendor in 2016, created the required specifications for selecting a new drug testing vendor, and revised DOCCS' Urinalysis Testing directive. Notably, the investigation found that Bedard, who lacked any scientific or legal education or training, was not qualified to evaluate the drug testing systems of the vendors that participated in the procurement.⁵¹

In December 2016, after discovering issues with DOCCS' earlier procurement of drug testing systems from Siemens, Bedard began to seek other vendors for the program. In furtherance of this effort, in 2017, Bedard requested that Microgenics salesperson Collum coordinate a side-by-side comparison of Siemens' and Microgenics' instruments and tests. According to Bedard, he chose to compare the instruments and tests manufactured by only two vendors—Siemens and Microgenics, “even though there were other vendors that were out there claiming that they could provide us the services” sought.⁵²

Bedard testified that the results of the comparison showed the two manufacturers' testing systems were essentially the same but for “one discrepancy.” Microgenics' testing systems found one urine sample was positive—and therefore was found to contain buprenorphine, while the same sample tested negative using Siemen's drug testing systems. Microgenics concluded that its test result had been incorrect, claiming the urine sample likely contained Tylenol with codeine, a medication prescribed to the incarcerated individual, which had cross reacted with its test. Microgenics representatives advised Bedard that the matter would be remedied if DOCCS were to procure its new test, the Buprenorphine II test. However, this test had yet to receive FDA approval or been prepared for marketing.

In anticipation of DOCCS' switch to Microgenics' drug testing systems, Bedard then took steps to revise DOCCS' Urinalysis Testing policy, which at the time referenced only Siemen's drug testing systems. In October 2018, with the assistance of Microgenics salesperson Collum, Bedard revised the policy to, in essence, equate Siemen's and Microgenics' testing systems so that the court's holding in *Peranzo* would be applicable. Collum provided quotes

⁵¹ Bedard testified to the Inspector General that “the science behind all this is not my forte.”

⁵² Two other vendors, Alere, Inc. (now known as Abbott Laboratories) and Alliance Laboratories also submitted bids to DOCCS under this procurement.

from scientific journals that spoke to the reliability of Microgenics' tests and analogized the results of the two tests. However, the Inspector General found no evidence that Bedard sought review of his policy changes by scientific experts or DOCCS' medical personnel.⁵³ Subsequently, DOCCS awarded the drug testing system contract to Microgenics.

The investigation found that at the time of the award, Microgenics' Buprenorphine II testing system was not being used by any other correctional system in the country.⁵⁴ Additionally, the investigation found that DOCCS was one of only seven states that disciplines incarcerated individuals based on the results of preliminary drug screening tests without confirming those results with a more specific alternate method.⁵⁵ DOCCS presented no evidence to the Inspector General that it was aware of these facts or had contacted other states to obtain information about confirmatory testing.

Bedard's errors, which were due to his inexperience and the lack of oversight by his supervisors, were heightened by DOCCS' failure to provide adequate procurement guidance and review by all necessary parties. Bedard testified that he merely intended to acquire instruments, tests, and services similar to those historically provided to DOCCS by Siemens, and Microgenics offered the analyzers and tests at lower costs. Unfortunately, Bedard and DOCCS failed to fully examine their internal practices to the detriment of the incarcerated individuals.

ADMINISTRATIVE FAILURES AFFECTED THE OPERATIONS OF THE INCARCERATED INDIVIDUAL DRUG TESTING PROGRAM

Testing Officers Neglected to Consistently Record Testing Results in Internal Database

The investigation found that although DOCCS' Urinalysis Testing policy requires testing officers to enter certain information on drug test results in an internal disciplinary tracking database, such officers often neglected to enter all required information.⁵⁶ Specifically, testing officers did not consistently record the specific rule an individual was found to have violated. As a result, when DOCCS attempted to identify all individuals who were disciplined based on

⁵³ This policy, found in Directive 4937, was approved by then Deputy Commissioner James O'Gorman.

⁵⁴ According to Microgenics, its products at this time were being used by the Arkansas and Hawaii Departments of Corrections, Georgia Department of Community Supervision, Federal Probation and Parole, and various state crime labs and drug courts throughout the country.

⁵⁵ The Inspector General reviewed publicly available drug testing policies for incarcerated individuals nationwide. This review found that 35 states have policies requiring confirmation, or permitting confirmation in specific circumstances, of preliminary screening urine tests prior to disciplinary action, and seven states did not require confirmation testing prior to disciplinary action. The Inspector General was unable to determine the drug testing policies for the remaining eight states.

⁵⁶ Directive 4937(VI).

positive results of Microgenics' drug tests, they were initially unable to do so using the information contained in the database. Consequently, DOCCS resorted to manually searching through hearing records to identify all individuals disciplined due to positive results of Microgenics' drug tests. This physical search took DOCCS almost three months to complete.

Testing Officers Neglected to Consistently Consult Medical Staff on Possible Cross-Reacting Drugs

Although DOCCS policy requires testing staff to consult with DOCCS medical staff concerning whether an incarcerated individual was prescribed any medication that could cause a false positive drug test result, this procedure was not consistently followed.⁵⁷ The investigation found that compliance with this policy varied among DOCCS' correctional facilities. Moreover, DOCCS had no procedure or uniform practice for its medical staff to review drugs prescribed by the New York State Office of Mental Health (OMH) to incarcerated individuals receiving mental health care. The Inspector General found the failure to have medical staff consistently review all medications prescribed to individuals to eliminate possible concerns of cross reactivity is alarming.⁵⁸

DOCCS Failed to Adequately Train Incarcerated Individual Drug Testing Staff and Hearing Officers

The investigation found that DOCCS failed to adequately train its drug testing and hearing officers, who generally did not understand the scientific operation of the drug tests and instruments utilized by DOCCS. In testimony to the Inspector General by testing and hearing officers and from a review of recordings of disciplinary hearings, this deficiency was evident.

DOCCS' drug testing officers responsible for administering DOCCS' Incarcerated Individual Drug Testing Program received only two days of training on the operation of Microgenics' drug testing instruments when the machines were first installed in DOCCS' facilities. No training was provided to the officers on the science behind the drug testing system.

After a measurable increase in positive test results was observed following the installation of Microgenics' drug testing systems in DOCCS' facilities in early 2019, few testing officers recognized this issue and elevated concerns to supervisors and executive staff. Indeed, several witnesses testified that they assumed the increase was due to the fact that Microgenics'

⁵⁷ Directive 4937(IV)(D)(2).

⁵⁸ DOCCS could not provide the total number of incarcerated individuals who received services from the New York State Office of Mental Health (OMH) and were disciplined for positive drug test results.

systems were better and more sensitive. No action was taken at any level within DOCCS to consider if the increase in positive test results could be linked to cross-reactivity or other factors.

Further, DOCCS' hearing officers, who are responsible for making determinations of fact on whether incarcerated individuals have used illegal drugs, received no training on testing technology. The investigation found that hearing officers often failed to understand arguments made by incarcerated individuals and explanations provided by Microgenics technical service representatives concerning testing technology. In fact, the Inspector General reviewed 30 recorded disciplinary hearings in which it appeared hearing officers did not understand the reliability of preliminary drug screening tests, the need for confirmatory testing, and cross-reactivity. These failures placed incarcerated individuals at a disadvantage when advocating for their innocence.

MICROGENICS FAILED TO DISCLOSE ISSUES WITH ITS URINALYSIS TESTS AND ITS REPRESENTATIVES PROVIDED MISLEADING INFORMATION DURING DOCCS' DISCIPLINARY HEARINGS

The Inspector General's investigation found that in 2019, Microgenics failed to disclose to DOCCS that its Buprenorphine II test had produced four false positive results when testing six DOCCS urine samples, and that internal research had shown the test was susceptible to cross-reactivity with some common medications and might thereby produce false positive results.

Microgenics Failed to Disclose to DOCCS Information on False Positive Test Results

In July 2019, as incarcerated individuals' complaints of false positive drug test results increased, Booth, who assumed oversight of DOCCS' Incarcerated Individual Drug Testing Program in January 2019, contacted Microgenics to request its assistance with evaluating these claims. Booth provided Microgenics with urine samples from six individuals who had tested positive for buprenorphine using Microgenics' Buprenorphine II test.

Microgenics retested the six urine samples using its Buprenorphine II test and all returned positive results. Microgenics then tested the six samples using what it purports to be a less sensitive test, its Buprenorphine I test. These tests produced different results—two positive, two “borderline” positive, and two negative test results.

Microgenics then sent the six urine samples to two outside laboratories for confirmation testing using Gas Chromatography – Mass Spectrometry. The first laboratory found that two urine samples contained buprenorphine, confirming the results found for those two urine samples

using both the Buprenorphine I and II tests. However, strikingly dissimilar to the positive results of the earlier Buprenorphine II tests, the first lab found that the four remaining urine samples were negative for buprenorphine at the specified cut-off value.⁵⁹ The second laboratory had the same findings as the first laboratory, but further found that two of the negative samples had *no* detectable buprenorphine or its metabolites.

In all, the confirmatory testing mandated by Microgenics—which DOCCS had neglected to obtain since Microgenics drug tests and instruments were installed at DOCCS’ correctional facilities beginning in January 2019—had found that four of six urine samples had returned false positives. Despite this unacceptable finding and contrary to the very purpose of Microgenics’ review, which was to assist DOCCS in discovering what might be causing false positive test results, Microgenics failed to disclose these findings to DOCCS.

Notably, the first outside laboratory’s results were received by Microgenics on September 4, 2019, the same day that DOCCS and Microgenics held a conference call specifically to discuss incarcerated individuals’ claims of false positives results by the Buprenorphine II test. Rather than reveal the apparent unreliability of its Buprenorphine II test, Microgenics instead recommended to DOCCS that it begin to use its older, less sensitive test, the Buprenorphine I test.⁶⁰

Microgenics’ Internal Research Finds but Does Not Disclose to DOCCS that its Buprenorphine II Test is Susceptible to Cross-Reactivity with Some Common Medications

Microgenics also failed to disclose to DOCCS that internal research had found that some common medications prescribed to incarcerated individuals and other common substances ingested by them might cross-react with its test reagents and cause false positive results when using the Buprenorphine II test. In addition, Microgenics did not advise DOCCS that its research had found that high doses of commonly prescribed medications might cause false

⁵⁹ Diagnostic drug tests set “cut-off values” to distinguish positive from negative samples. Samples testing at or above a cut-off value are considered positive, while samples testing below are considered negative. Of note, the first laboratory also tested the four samples for norbuprenorphine, a metabolite of buprenorphine, and likewise found it was not present at the Buprenorphine II test cut-off value.

⁶⁰ As DOCCS’ Incarcerated Individual Drug Testing Program had been suspended by this date, DOCCS did not use Microgenics’ Buprenorphine I test.

positive results. For example, the medications Codeine, Dextromethorphan (a cough suppressant), and Oxycodone might cause false positive results if taken in higher doses.⁶¹

In July 2019, DOCCS provided Microgenics with a list of medications commonly prescribed to individuals at one of its correctional facilities and requested that Microgenics determine if the medications could factor into potential false positive drug test results. As noted earlier in this report, Microgenics' tests include a package insert which lists, among other information, substances that have been found to cross-react with the test and thereby potentially cause false positive test results. Some of the medications on the list provided by DOCCS were not listed on Microgenics' package insert as identified cross-reactive substances. However, Microgenics advised that some of the prescribed medications, while not tested by Microgenics, have a "high probability of interference" and therefore could cause a false positive test result. These medications included Omeprazole (an antacid), Naproxen (a commonly prescribed pain reliever), and a "multivitamin tab," among others.

According to Microgenics, it tests substances for cross-reactivity after the product is brought to market, and it may receive requests from customers, field technicians, or technical support to test particular substances. Microgenics reviewed the list and identified three substances that cross-react with the Buprenorphine II test but were not listed on package inserts. These substances, which included metabolites of a commonly prescribed antacid and a natural sweetener, could return a false positive result.⁶² However, Microgenics never notified DOCCS of this finding. Microgenics advised the Inspector General that it had not disclosed these new findings because they were "preliminary screening results" that had not been verified by the FDA. Microgenics claimed that it relies on FDA review and approval as part of its decision making about whether to disclose test results and findings to customers.

Microgenics Representatives Provided Misleading and Inconsistent Information to DOCCS and Incarcerated Individuals at Disciplinary Hearings

The investigation found that Microgenics representatives provided misleading and inconsistent statements during disciplinary hearings for individuals incarcerated with DOCCS.

⁶¹ The substances listed on Microgenics' package inserts only disclose the highest amount of a substance known to produce a *negative* result. Microgenics does not disclose the amount of a substance that would produce a positive result.

⁶² The substances were two metabolites of Omeprazole, a commonly prescribed antacid, and one metabolite of a compound found in Stevia, a natural sweetener. This antacid was found to cross-react at 25,000 ng/mL compared to most substances listed on the package insert that were found not to cross-react at levels up to 100,000 ng/mL.

Specifically, while participating at these hearings, Microgenics representatives failed to verify that positive preliminary drug screening test results must be confirmed by a more specific alternative method. This contention was true even in instances where incarcerated individuals pointed out that such confirmation testing was mandated in instructions provided with all Microgenics tests. Moreover, the investigation found that Microgenics Sales Representative Collum instructed company representatives not to discuss confirmatory testing during DOCCS' hearings.

Pursuant to its contract with DOCCS, Microgenics representatives staffed a telephone hotline and provided answers to questions posed during disciplinary hearings about Microgenics' instruments and tests.

The Inspector General reviewed recordings of approximately 30 disciplinary hearings made during the relevant period and identified several in which incarcerated individuals asked the representatives if positive results found using Microgenics tests required confirmation. In response, Microgenics representatives failed to verify the need for confirmatory testing and often replied that DOCCS was responsible for determining whether such tests must be confirmed.

In a July 2019 disciplinary hearing the following exchange took place:

Incarc. Indiv: My following question, sir, has to do with your documentation specific for the CEDIA buprenorphine assay. It says, my question is, isn't it true that official documentation of your company Thermo Fisher Scientific clearly states that this machine utilizes, the study of buprenorphine assay is for screening purposes only?

Hearing Off: Here, let me see that. His question is, the documentation that he has in front of him shows that the machine that we are using is a preliminary analytical test. Is that true?

Micro. Rep: For normal use, yes. For government use, though, that is dependent on the site. The information we see is what we [inaudible] available on our website. That is normally used by like a pain clinic other . . .

Incarc. Indiv: Sir, that is not my question.

Micro. Rep: Other hospitals and pain clinics, those are governed by, by a different set of rules. For government facilities, it is up to them as to . . . operating procedures . . . It's really up to the facility . . . government entities like the New York Department of Corrections . . . they don't always have to comply with what we'd, what's normally released for our non-government entities.

Incarc. Indiv: Yeah, I'm sorry, but that's not what it says in the document, sir. The document says that the assay will provide you with preliminary analytical test results. It doesn't say anything about hospitals or prisons or law enforcement or non-law enforcement use, it says that it provides only preliminary analytical test and more specific alternative careful methods must be used, not should be, must be used, to confirm any analytical results and then they recommend gas chromatographic mass spectrometry is the preferred confirmatory method. Is that true?

Micro. Rep: For pain clinics and [inaudible], yes.

Incarc. Indiv: That's not what it says in the document, sir.

Micro. Rep: I know what it says on the document. I have it in front of me.

Incarc. Indiv: So do I, sir.

Hearing Off: So, do you have any other questions for him?

Incarc. Indiv: Yes. Why must it be confirmed by a second GCMS test?

Hearing Off: The question is that with this testing procedure, and it says here, more specific alternative method must be used to obtain a confirmed analytical result. Is that true?

Micro. Rep: Only if there's a need to know the specific level of buprenorphine that's in the system. . . It's used by pain clinics to determine if a customer or the patient is compliant with their current regimen of, say, in this case, buprenorphine. If they're being prescribed suboxone, which is to help them get off of opioids, there needs to be a critical level of buprenorphine in their system. And LCMS is one way that you could determine the exact amount, that way the pain clinic knows that they're not saving their pills and that they're taking enough to get a positive and not giving enough of the buprenorphine in their system to show that they've really taken the pills in.

The incarcerated individual quoted above justifiably asked about the type of drug testing during the disciplinary hearing. However, the hearing officer misconstrued the question and the Microgenics representative failed to verify the need for confirmatory testing. In this matter, the hearing officer ultimately "found discrepancies" and found this incarcerated individual not guilty.

In testimony to the Inspector General, this Microgenics representative stated that confirmation testing only applied to medical clinics, where the quantity of a drug present in a

urine sample must be determined. According to the representative, as DOCCS only needed to know whether an incarcerated individual's sample was positive or negative, no such confirmation testing was required. This testimony by the vendor's representative contradicts the instructions Microgenics provides with all drug tests.

Additionally, the Inspector General found no evidence that the requirement of confirmatory testing was conditioned on the type of facility using the tests. Notably, other Microgenics personnel interviewed by the Inspector General advised that the tests used by DOCCS were preliminary drug screening tests that must be confirmed.

The Microgenics representative further testified that when DOCCS awarded its drug testing contract to Microgenics, Collum instructed the technical service representatives that DOCCS does not perform confirmatory testing and therefore it should not be discussed by the representatives during incarcerated individual hearings. Collum denied this statement in testimony to the Inspector General. Such instruction, if given, would have almost certainly hindered the responses of these representatives to questions raised by incarcerated individuals during their disciplinary hearings.

The Inspector General also found that Microgenics representatives—on multiple occasions—provided other misleading or inconsistent information in disciplinary hearings.

In one example, in March 2019, an incarcerated individual questioned a Microgenics representative about the reliability of the preliminary drug screening tests. This individual, who denied using buprenorphine, had never before failed a urine screening test while incarcerated with DOCCS. The Microgenics representative advised the individual that the test was 99.9 percent accurate, and he could not recall ever seeing a false positive result. No mention was made of confirmatory testing. This individual was found guilty and ultimately sentenced to 40 days keeplock; 75 days loss of recreation and package, telephone, and commissary privileges; and a two-month loss of good time was recommended.

In another example, an incarcerated individual who tested positive for buprenorphine in February 2019 questioned a Microgenics representative about possible cross-reactions with over-the-counter medications. The representative advised the individual that over-the-counter drugs would not cause a false positive and “anything that would cause a positive would be some sort of variation of buprenorphine or . . . something chemically related.” This is incorrect. Nevertheless, this individual was found guilty and sentenced to 180 days in SHU; 180 days loss

of recreation and package, telephone, and commissary privileges; and a 30-day loss of good time was recommended. He was also referred to DOCCS' Alcohol and Substance Abuse Treatment Program.

FINDINGS AND RECOMMENDATIONS

DOCCS Disciplined Incarcerated Individuals Based Solely on Preliminary Drug Screening Test Results

The Inspector General's investigation found the DOCCS disciplined incarcerated individuals based on the results of preliminary and unconfirmed drug screening tests. Despite instruction included with all Microgenics drug tests that require a "more specific alternative chemical method must be used to obtain a confirmed analytical result," this did not occur.

During the eight-month period in which Microgenics' drug testing systems were used at DOCCS, 3,018 incarcerated individuals tested positive for drug use, with 2,199 incarcerated individuals testing positive for buprenorphine, 1,632 of which were charged and punished.⁶³

Punishment for these individuals included solitary confinement in SHU and keeplock, delays in parole eligibility and/or release, and/or the loss of privileges such as the receipt of packages, commissary, telephone use, and participation in the Family Reunion Program and other programs.

Bedard unreasonably relied on three-decade old case law—with holdings based on another manufacturer's drug test—to forgo confirmatory testing of preliminary drug screening test results obtained using the new Microgenics drug testing systems. This reliance was misplaced and not appropriately reviewed by DOCCS' Counsel's Office or medical examiner. Additionally, the court in the *Peranzo* case did not consider cross-reacting substances possibly found in incarcerated individual urine samples.

During the investigation, the Inspector General recommended to DOCCS that it confirm the results of all urine tests prior to taking disciplinary action. DOCCS advised the Inspector General that on January 15, 2020, it terminated its contract with Microgenics.

On February 22, 2021, DOCCS resumed its Incarcerated Individual Drug Testing Program following a revised Urinalysis Testing Policy requiring that "all initial positive test results will be sent to the outside laboratory for confirmation testing." DOCCS now uses a

⁶³ DOCCS' internal disciplinary database does not track whether an incarcerated individual's punishment is based upon a positive drug test alone or includes some other charge.

preliminary drug screening test known as the Premier Biotech Bio-Cup to test urine samples. Positive results from these preliminary drug screening tests are then tested using a more specific alternative method, Gas Chromatography – Mass Spectrometry, by Cordant Health Solutions.

During the investigation, the Inspector General advised DOCCS to release from internal confinement any individuals then-currently confined solely based upon positive drug screening results. Between September 11, 2019 and October 22, 2019, DOCCS released 140 incarcerated individuals from confinement that met these conditions.

The Inspector General also advised DOCCS to reverse and expunge all records of incarcerated individuals who were found guilty of drug consumption based upon a Microgenics preliminary screening test. DOCCS advised that it subsequently reversed and expunged approximately 2,500 disciplinary records.

In light of the termination of the Microgenics contract and the restructuring of the Incarcerated Individual Drug Testing Program, the Inspector General recommends that DOCCS review its policies to ensure that DOCCS medical and legal staff review and approve any future modifications to the program.

DOCCS Failed to Take Prompt Corrective Action Upon Learning Some Incarcerated Individuals Had Been Charged with Drug Violations and Punished Due to False Positive Drug Screening Test Results

Former DOCCS Associate Commissioner Kelly failed to take prompt corrective action after discovering that at least five incarcerated individuals had been wrongfully charged and punished for drug violations. Kelly retired from State service in August 2020, while this investigation was pending.

DOCCS Likely Improperly Procured its Drug Testing Systems and Services

DOCCS procured its drug testing systems and services and entered into lease agreements for drug testing instruments in apparent violation of State Finance Law. Moreover, DOCCS did not perform due diligence when contracting with Microgenics for its drug testing systems, failing to understand that such tests were merely preliminary screening tests that would require confirmatory testing. The Corrections division of DOCCS also failed to coordinate with the Community Supervision division to leverage the use of existing resources, which would have allowed Corrections to use the same vendor to cut costs and streamline processes.

The Inspector General recommends that DOCCS undertake a review of its Contract Procurement Unit's processes to ensure compliance with State Finance Law in all procurements. Additionally, DOCCS' Counsel's Office should review and approve all contracts and purchase orders over a designated monetary threshold set by the agency after an internal review is conducted.

Administrative Failures Affected the Operations of the Incarcerated Individual Drug Testing Program

DOCCS engaged in various administrative failures in the Incarcerated Individual Drug Testing Program that affected the operations of the program. These included the failure by testing officers to enter all required information into a central disciplinary tracking database, and to consistently consult medical staff on possible cross-reacting drugs—as is required by policy. Also, the investigation found DOCCS did not adequately train drug testing staff and hearing officers on the drug tests and instruments. Additionally, DOCCS had no procedure or uniform practice for its medical staff to review drugs prescribed by OMH to incarcerated individuals receiving mental health care.

The Inspector General recommends that DOCCS provide comprehensive training to its drug testing and hearing officers on the drug testing policy, tests, and instruments used in the program. In addition, testing and hearing officers should be reminded of the requirement to enter all required drug testing information into DOCCS' disciplinary tracking database and to consistently consult medical staff on possible cross-reacting drugs. DOCCS must also ensure that when incarcerated individuals test positive for illegal drug use, its medical staff reviews drugs prescribed by OMH for those individuals receiving treatment. DOCCS should also evaluate its disciplinary hearings database to determine if other information should be captured including the type of violation and other agencies involved.

Microgenics Withheld Information from DOCCS Concerning False Positive Test Results and Research Involving its Drug Testing Systems and Provided Misleading and Inconsistent Statements during DOCCS' Incarcerated Individual Disciplinary Hearings

Microgenics failed to disclose to DOCCS issues it discovered with its urinalysis tests, and Microgenics representatives provided incorrect and misleading information during DOCCS' disciplinary hearings. Namely, when Microgenics discovered that its Buprenorphine II test had produced four false positive results when testing six individuals' urine samples, it did not advise DOCCS of these results. And when Microgenics' internal research revealed that one of its drug

tests was susceptible to cross-reactivity with some common medications and might thereby produce false positive results, it again did not advise DOCCS of this fact. Additionally, when Microgenics representatives provided responses to incarcerated individuals' questions during disciplinary hearings, the information provided was sometimes misleading and incorrect and the representatives never advised incarcerated individuals that Microgenics' preliminary drug screening tests required confirmation testing by more specific alternate methods.

DOCCS' RESPONSE TO THE INSPECTOR GENERAL'S INVESTIGATION AND REPORT

DOCCS advised the Inspector General that it has adopted and is implementing all of the Inspector General's recommendations.

Additionally, DOCCS advised that it undertook a comprehensive review of all possible adverse impacts on the incarcerated population to determine what remedial actions were necessary to make whole each incarcerated individual that was potentially affected by an expunged disciplinary ticket for Drug Use regardless of the substance. That review resulted in approximately 2,500 disciplinary records expunged followed by the proactive removal or redaction of over 2,100 impacted records related to transfer orders and substance abuse treatment.

According to DOCCS, in addition to the remedial steps outlined below, DOCCS eliminated segregated confinement as a potential sanction for Drug Use disciplinary violations starting December 1, 2020. DOCCS further advised that many of the remedial actions taken required intensive collaboration across DOCCS, including but not limited to: immediate release from segregated confinement; de novo interview with the Board of Parole; reassessed open date for release; return of lost good time credit or merit consideration; reinstatement to temporary work release; return to the CASAT program; return to college or other academic/vocational programs; reassessed status in substance abuse treatment programing; reinstatement to sex offender treatment; removed visitation sanctions and restrictions; reassessed Family Reunion Program applications; payment of lost incarcerated individual wages; and return to an area of preference facility. Lastly, DOCCS advised that each category of remedial action was actively monitored by the Commissioner's Task Force.

Addendum 1

ELIZABETHSPRATT, MS, F-ABFT

Forensic Toxicology Services
420 South Riverside Avenue, #282
Croton-on-Hudson, NY 10520

Telephone: (914) 274-8858
Cell: (914) 275-8351
Fax: (914) 271-8717

Experience

Forensic Toxicology Services

January 2000 to Present

Providing wide range of Forensic Toxicology consulting services in both criminal and civil areas including DWI/DWAI and DFSA, insurance claims, Dram shop casework and court testimony. Serve as inspector for Workplace Drug Testing, Department of Defense, and American Board of Forensic Toxicology Laboratories. Lecturer for professional and community groups regarding toxicological issues.

Director of Toxicology

January 2006 to January 2019

Westchester County Department of Labs and Research
Valhalla, NY

Chief of Toxicological Services

August 1990 to December 2005

Senior Toxicologist

October 1986 to August 1990

Responsible for Forensic Toxicology Analyses. Duties include supervising activities of full service forensic toxicology laboratory which serves Westchester County's medicolegal needs. Work comprises legal drug screening and blood alcohol determinations for local, county, and New York State Police as well as methods development. Involved in Medical Examiner's, DWI/DWAI, and DFSA cases and providing expert testimony in judicial hearings. Responsible for ABFT (American Board of Forensic Toxicologists), and ASCLD (American Society of Crime Lab Directors) accreditation in the laboratory. Instrumentation includes GC/MS, GC/FID, HPLC, LC/MS, LC/MS/MS, LC/MS-TOF, UV and TLC.

Research Scientist; Pharmaceutical Development

November 1981 to October 1986

Ortho Pharmaceutical Corporation
Raritan, NJ

Supervised Process Validation Group, Pharmaceutical Analysis. Responsibilities include interfacing with Process Development for analytical testing; methods development for cleaning; and analytical troubleshooting for production using HPLC, GC, UV and TLC.

Pilot Manager; White Collar Productivity Improvement Program

January 1985 to October 1986

This project evaluated all services provided by the entire Pharmaceutical Development Division and resulted in the proposal and initiation of action plans to improve the delivery of these services.

Technical Supervisor; Toxicology, Special Chemistry

April 1978 to October 1981

Hospital of the University of Pennsylvania
Philadelphia, PA

Managed department activities: methods development, routine toxicology, special chemistry and research. Techniques included GC, UV, HPLC, EMIT, fluorometry, and AA. Other duties: QC, proficiency testing, regulatory compliance, methods and instrumentation troubleshooting. Coordinated contracted projects from outside agencies. Supervised daily activities of seven technologists.

Toxicologist; Laboratory Procedures East

September 1974 to April 1978

The Upjohn Company

King of Prussia, PA

Supervised day and night shifts of technical staff of eight. Responsible for all legal analyses, QC, and proficiency testing. Used standard laboratory analytical methods and instrumentation including ASV and RIA.

Toxicologist

May 1972 to September 1974

Allegheny County (PA) Coroner's Office

Pittsburgh, PA

Qualitative and quantitative analyses of drugs and toxic substances in blood, urine, and unidentified samples were performed on coroners' cases, overdoses and emergency night calls.

Education**M.S., Pharmacology/Toxicology**

September 1972 to May 1974

Duquesne University

Pittsburgh, PA

Thesis: "Interfering Compounds in Urine Screening for Drugs"

B.S., Chemistry

September 1968 to May 1972

Duquesne University

Pittsburgh, PA

Certifications

Forensic Toxicology, Fellow (1/15)

Forensic Toxicology, Diplomate (1/02)

Forensic Toxicology Specialist

Toxicological Chemist

Blood and Urine Alcohol Analysis

Breath Analysis Operator: Breathalyzer, Intoxilyzer, Data-master, Datamaster DMT, Draeger Alcotest 7110 MKIII, and Alcotest 9510

American Board of Forensic Toxicology (F-ABFT)

American Board of Forensic Toxicology (DABFT)

American Board of Forensic Toxicology (FTS-ABFT)

National Registry of Certified Chemists (1989)

NY State Department of Health

NY State Department of Health

Federal Inspector

National Laboratory Certification Program (formerly NIDA)

Laboratory Inspector

American Board of Forensic Toxicology

U.S. Department of Defense Urine Testing Program

Laboratory Inspector (former)

American Society of Crime Lab Directors (ASCLD)

Professional Society and Committee Memberships

American Board of Forensic Toxicology (member, Board of Directors, June 8, 2008 to June 30, 2017) New York State Crime Laboratory Advisory Committee (NYCLAC)

Society of Forensic

Toxicologists

American Academy of

Forensic Sciences

American Association of Certified Chemists

The International Association of Forensic Toxicologists

Technical Working Group, Toxicology (TWGTOX,

New York State) SWGTOX (Scientific Working

Group Toxicology, Federal Committee) Impaired

Driving Advisory Council (NYS)

Publications

A Fatality Due to Accidental Pinesol® Ingestion; *JAT* 24:7, p664 (October 2000)

A Fatality Related to the Veterinary Anesthetic Telazol®; *JAT* 23:6, p552 (October 1999)

LC/MS with a Particle Beam Interface; *Forensic Toxicology, Clinics in Laboratory Medicine* 18:4,651 (December 1998)

Elizabeth Spratt M.S., F-ABFT

Curriculum Vitae

Certifications:

American Board of Forensic Toxicology - Fellow 1/2015

American Board of Forensic Toxicology- Diplomate 1/2002

American Board of Forensic Toxicology- Forensic Toxicology Specialist

US Depart. of Human & Health Services/Inspector HHS National Laboratory Certification Program

National Registry in Certified Chemistry-Toxicological Chemist

Breath Instrument Certifications/expertise: Datamaster, Intox-4011ASA, Breathalyzer 900/900A and Draeger Alcotest 7110 MK III, Datamaster DMT, Alcotest 9510

Certified by New York Department of Health: Blood and Urine Permit Testing for DWI/DWAI Samples- 1986-2019

Certified Trainer for Saliva Alcohol Testing (12/95)

PUBLICATIONS

"An Unusually High Level of Barium in a Prison Fatality"
Case Note – ToxTalk: Volume 28 No. 3 (September 2004)

"A Fatality Due to Accidental PineSol Ingestion"
JAT 24:7, 664-666 (October 2000)

"A Fatality Related to the Veterinary Anesthetic Telazol"
JAT 21(6): 552-555 (10/99)

"LC/MS with a Particle Beam Interface in Forensic Toxicology"
Clinics in Laboratory Medicine 18(4): 651-663 (1998) 12/98

Presentations/Lectures

Diane Schuler Parkway Tragedy
New Rochelle High School Forensic Class
New Rochelle, NY (Zoom Presentation)
June 5, 2020

Alcohol and Drugs, Facts and Fiction
18B and Legal Aid Attorneys
Suffolk County Bar Association
Hauppauge, NY
May 16, 2019

New Drugs Detected in Westchester County and Aspects of the
Diane Schuler Parkway Tragedy
New Rochelle High School Forensic Class

New Rochelle, NY
April 9, 2019

New Drugs Detected in Westchester County and Aspects of the
Diane Schuler Parkway Tragedy
New Rochelle High School Forensic Class
New Rochelle, NY
December 14, 2017

New Drugs in Westchester County and Aspects of the
Diane Schuler Parkway Tragedy
New Rochelle High School Forensic Class
New Rochelle, NY
April 27, 2017

Forensic Toxicology in New York State, 2016 Report
Traffic Safety Committee
White Plains, NY
December 6, 2017

Heroin Overdose Response Initiative in Westchester County
Westchester County Response Team
Valhalla, NY
October 23, 2017

Toxicology Update in Westchester County
Student Assistant Services Corporation
White Plains, NY
August 15, 2017

Forensic Toxicology Cases in Westchester County and Aspects of the
Diane Schuler Parkway Tragedy
New Rochelle High School Forensic Class
New Rochelle, NY
April 27, 2017

Forensic Toxicology Cases in Westchester County and Aspects of the
Diane Schuler Parkway Tragedy
New Rochelle High School Forensic Class
New Rochelle, NY
February 12, 2016

Forensic Toxicology in Westchester County
District Attorney Continuing Education Seminar
White Plains, NY
June 14, 2013

Diane Schuler Taconic Parkway Crash
NEAFS Annual Meeting
Saratoga Springs, NY
November 16, 2012

Forensic Toxicology in Westchester County and Aspects of the
Diane Schuler Parkway Tragedy
Kendal Way Association

Sleepy Hollow, NY
March 29, 2010

Speaker at Westchester County Breath Instrument Training/Certification
Testimony for Breath Instruments and Toxicology Submissions
Westchester County Police Academy Training Center
Valhalla, NY
January 7, 2010

Speaker at Dutchess County Annual Law Enforcement Ceremony/Luncheon
Toxicology and the Diane Schuler Case
Dutchess County Stop DWI
Wappingers Falls, NY
November 13, 2009

Preparation for the ABFT Examination
Analytical Techniques
Society of Forensic Toxicologists Meeting
Oklahoma City, OK
October 19, 2009

Trends in Toxicology- Blood/Urine in Westchester County
Region One: GTSC-Drug Recognition Expert
Recertification/Training
Valhalla, NY
June 9, 2009

Everything You Wanted to Know About Forensic Toxicology
WMC Dept. of Pathology Resident Training Conference
Westchester Medical Center
Valhalla, NY
May 15, 2009

Understanding the Toxicology of DWI/DWAI Cases
Westchester County District Attorney's Office
White Plains, NY
January 9, 2009

Toxicological Aspects of Crime Scene Evidence
Advanced Crime Scene Investigation Seminar
October 22, 2007

Toxicological Aspects of Crime Scene Evidence
Advanced Crime Scene Investigation Seminar
June 7, 2007

Cocaine and Driving Impairment
Interpretive DUID Workshop
SOFT Continuing Education Cmte. & SOFT/AAFS Drugs &
Driving Committee Seminar
Albany, NY
May 22, 2007

Stimulants and Driving Impairment (MA/AMP – MDMA/MDA)
Interpretive DUID Workshop

SOFT Continuing Education Cmte. & SOFT/AAFS Drugs &
Driving Committee Seminar
Albany, NY
May 22, 2007

Toxicology in Westchester County
District Attorney's Office
White Plains, NY
January 10, 2007

Toxicology in Westchester County
Governor Traffic Safety Committee and
Nassau County District Attorney's Office
Horizontal Gaze Nystagmus (HGN) and Toxicology
Speaker and attendee
Mineola, NY
July 31, 2006

Toxicological Aspects of Crime Scene Evidence
Advanced Crime Scene Investigation Seminar
June 26, 2006

Toxicology in Drug Facilitated Sexual Assault Cases
The Forensic Education Project: Future Solutions...Now
NYSCASA
Criminal Justice Collaboration Project
Poughkeepsie, NY
February 28, 2006

Toxicological Aspects of Crime Scene Evidence
Advanced Crime Scene Investigation Seminar
November 14, 2005

Marijuana
Forensic Toxicology Review, sponsored by SOFT
Albany, NY
September 13, 2005

Antihistamines & NSAIDs
Forensic Toxicology Review, sponsored by SOFT
Albany, NY
September 13, 2005

Toxicological Aspects of Crime Scene Evidence
Advanced Crime Scene Investigation Seminar
June 7, 2005

DWI: Everything You Wanted To Know About Breath Instruments in Westchester County
Westchester County Bar Association
White Plains, NY
April 6, 2005

Becoming an Accredited Forensic Toxicology Laboratory
FBI Laboratory Symposium/SOFT

Washington, DC
August 30, 2004

Use of Breath Instruments in Driving While Intoxicated Cases
Mount Vernon Bar Association
Tuckahoe, NY
May 25, 2004

Toxicology in DWI Cases
New York Prosecutors Training Institute
Suffern, NY
February 23, 2004

Drug Facilitated Sexual Assault – Helping the victim while strengthening your case
New York State Coalition Against Sexual Assault
9/10/03 – New York Medical College, Valhalla, NY
9/23/03 – Bellevue Hospital Manhattan, NY
2/3/04 – Elmhurst Hospital, NY

Marijuana Abuse: Assessing Marijuana Abuse through Hair, Blood and Urine Testing

Student Assistant Services Corp. and Caron Foundation
Tarrytown, NY 12/03/02

Forensic Toxicology - What is it?
St. Joseph's College, Rensselaer, IN 3/11/02

Toxicology - preparation for ABC exam for Forensic Scientists
9/6/01

Issues in Toxicology
1999 NY State Conference on Impaired Driving Issues 11/17/99

Breath Alcohol Testing
Stop DWI Conference 9/18/99

Toxicology-Drugs Found in Rape Cases
Victims Assistance Services 7/14/99

"Drug Testing: The Myths vs. The Realities"

Student Assistant Services Liberty Management Inc.
Tarrytown, NY 12/98

"Suicide Solution: A Case Report to Highlight Versatility in Forensic Toxicology"
Northeastern Association of Forensic Scientists, Newport, RI 11/4/98

What is Toxicology?
Rye Neck Middle School, Women in Business Day 3/98, 3/00, 3/01, 3/02, 3/04

"Olanzapine: A Little or A lot, It All Depends on the Problems You've Got."
NEAFS, White Plains, NY 10/97

"LC/MS in Forensic Toxicology Drug Screening"
AAFS Annual Meeting 2/97

Acute Mixed Drug Overdose-Some Are and Some Are Not
AAFS Annual Meeting 2/95

Sertraline and Paroxetine Quantitation in Medical Examiner's Cases
SOFT Annual Meeting 11/94

Toxicology and Medical Examiner Testing
AlChemE (Alliance of Chemistry Educators) 10/1/94

Laboratory Testing and Procedures, Samples and Trends in Present Samples
Stop DWI Enforcement Conference 1992

Changing Patterns in Poly Drug Abuse: A Two Year Study 1992

A Survey of Coabuse of Alcohol and Cocaine 1992

Fluoxetine in Medical Examiner's Cases by GC/ITD 1992

The Effects of Solvents on the Intoxilyzer 4011AS-A
NEAFS Annual Meeting 1987
AAFS Annual Meeting 1989

Training Courses , Workshops and Seminars

Applied Pharmacodynamics 10/19-21/21
Center for Forensic Science Research & Education
Virtual 15 hours

NLCP Inspectors' Training - Virtual 9/26/21
SOFT Annual Meeting
Nashville, TN

Therapeutic use of Psychedelic Drugs 7/13/21
& Minimum Requirements for Drug Identification (6 hours)
The International Association of Forensic Toxicologists
Virtual

Cannabis Impaired Driving 9/22/20
SOFT Annual Meeting
Virtual

Oral Fluid Toxicology: Workplace Testing, Pain Management & DUID 10/15/19
SOFT Annual Meeting
San Antonio, TX

Driving Under the Influence: The NPS Edition 10/14/19
SOFT Annual Meeting
San Antonio, TX

Best Practices for Investigation of Overdose Deaths 10/14/19
SOFT Annual Meeting
San Antonio, TX

NLCP Inspectors' Training 10/13/19

SOFT Annual Meeting San Antonio, TX	
The American Academy of Forensic Sciences (AAFS) Responds to The Opioid Crisis AAFS Annual Meeting Baltimore, MD	2/20/19
The National Transportation Safety Board (NTSB): Understanding and Preventing Impairment in Transportation AAFS Annual Meeting Baltimore, MD	2/19/19
Novel Psychoactive Substance (NPS) Surveillance, Detection, And Intelligence for Use by Forensic Laboratories, Public Health and Public Safety AAFS Annual Meeting Baltimore, MD	2/18/19
NLCP Inspectors' Training SOFT Annual Meeting Minneapolis, MN	10/7/18
"Can We Say That" – Drug Impaired Driving Testimony SOFT Annual Meeting Minneapolis, MN	10/8/18
Incorporating the Updated NSC ADID Lab Guidelines into Casework: Pharmacology, Methodologies and Case Reports for Buprenorphine, Fentanyl And Tramadol SOFT Annual Meeting Minneapolis, MN	10/9/18
Keeping Pace in the NPS Race: US Resources and Trends SOFT Annual Meeting (Delayed from September) Boca Raton, FL	1/8/18
Toxicological Investigation of Deaths in Alberta Due to Fentanyl, Its Analogues and other Opioids SOFT Annual Meeting (Delayed from September – Lunch Seminar) Boca Raton, FL	1/8/18
High Resolution Mass Spectrometry Techniques to Detect Fentanyl Analogues SOFT Annual Meeting (Delayed from September – Lunch Seminar) Boca Raton, FL	1/7/18
Cannabis in DUID Investigations SOFT Annual Meeting (Delayed from September) Boca Raton, FL	1/7/18
NLCP Inspectors' Training 2017 Virtual Inspector/Lab Director Virtual Workshop	9/15/17

Interpreting Blood Cannabinoids: Markers of Recent Use Webinar, Sponsored by National Medical Services	8/22/17
Latent Cause Analysis DCJS Sponsored Seminar Albany, NY	3/13/17
Conflict Resolution Seminar Westchester County EAP Valhalla, NY	12/7/2016
Opioids in DUID investigations SOFT Annual Meeting Dallas, TX	10/17/16
NLCP Inspectors' Training SOFT Annual Meeting Dallas, TX	10/16/16
Pharmacology and Toxicology of Synthetic Cathinones and Phenethylamines SOFT Annual Meeting Atlanta, GA	10/19/15
Management Practices in Forensic Toxicology: A Panel Discussion SOFT Annual Meeting Atlanta, GA	10/19/15
NLCP Inspectors' Training SOFT Annual Meeting Atlanta, GA	10/18/15
Implementing DUID Drug Recommendations SOFT Annual Meeting Grand Rapids, MI	10/20/14
NLCP Inspectors' Training SOFT Annual Meeting Grand Rapids, MI	10/19/14
NLCP Inspectors' Training SOFT Annual Meeting Orlando, FL	10/27/2013
Analytical Methods in Workplace Drug Testing – Mass Spectrometry RTI International Workshop	3/10/13
Analytical Methods in Workplace Drug Testing – Sample Preparation RTI International Workshop	10/14/12
Analytical Methods in Workplace Drug Testing - Immunoassay RTI International Workshop	10/14/12
Opioid Drugs: 21 st Century Killers SOFT Annual Meeting	7/2/12

Boston, MA	
NLCP Inspectors' Training SOFT Annual Meeting Boston, MA	7/1/12
Publishing in Journals for Forensic Toxicologists SOFT Annual Meeting San Francisco, CA	9/26/11
NLCP Inspectors' Training SOFT Annual Meeting San Francisco, CA	9/25/11
Marijuana, Pharmacology – Practical Applications for the Forensic Toxicologist SOFT Annual Meeting Richmond, VA	10/18/10
NLCP Inspectors' Training SOFT Annual Meeting Richmond, VA	10/17/10
Packaging and Shipping of Infectious Diseases Department of Labs and Research Valhalla, NY	10/7/10
Applications of LC/MS Technologies in Forensic Toxicology New York State DCJS and SOFT Albany, NY	9/27-28/10
K2 and Synthetic Cannabinoids, Effects and Chemical Analysis National Medical Services Web Seminar	9/16/10
Assessment and Interpretation of Toxicology in Neonatal, Pediatric and Geriatric Deaths AAFS Annual Meeting Seattle, WA	2/22/10
Applications of LC Mass Spectrometry Technologies in Forensic Toxicology Sponsors: NYS – DCJS and SOFT Albany, NY	9/27-28/10
Training and Operation of AU400 Autoanalyzer Labs & Research By ABS Scientific	8/5/10
LC/MSMS and GC/MS/MS Seminar Thermo Scientific Valhalla, NY	11/2/09
Ethics Training Sponsored by the Office of the Inspector General	10/28/09

Valhalla, NY	
NLCP Inspectors' Training SOFT Annual Meeting Oklahoma City, OK	10/18/09
Expert Witness Training NYS DCJS Office of Forensic Services Albany, NY	09/14/09
Strategies in Defending the DWI and DUI Cases Lorman Seminar Albany, NY	12/04/08
Stimulating Realm of Sympathomimetic Amines and Tryptamines Workshop SOFT Annual Meeting Phoenix, AZ	10/27/08
NLCP Inspectors' Training SOFT Annual Meeting Phoenix, AZ	10/26/08
NLCP Inspectors' Training SOFT Annual Meeting Durham, NC	10/14/07
Toxicology Jeopardy – DUID Testing Workshop SOFT Annual Meeting Durham, NC	10/16/07
Tox. Analysis of Drug Facilitated Crimes Workshop SOFT Annual Meeting Durham, NC	10/15/07
Beyond Herbals: The Toxicology of Plants Workshop SOFT Annual Meeting Durham, NC	10/15/07
Interpretive DUID Workshop SOFT Continuing Education Cmte. & SOFT/AAFS Drugs & Driving Committee Seminar Albany, NY	5/22-24/07
Driving While Intoxicated: Field Sobriety Testing And Breath Analysis Instrument Update Westchester County District Attorneys Officer Stewart Smith White Plains, NY	1/10/07
New Antidepressants & Antiepileptics: Clinical Pharmacology, Pharmacogenomics, Gene Expression and Neurobiology of Depression & Suicide & Forensic Toxicology Workshop SOFT Annual Meeting Austin, TX	10/04/06

Addiction and Pain Management for Forensic Toxicologists Update on Drug Therapy, Clinical and Forensic Workshop SOFT Annual Meeting Austin, TX	10/04/06
Doping, Testing for Doping Substances and the Organization Of Doping Control Efforts Workshop SOFT Annual Meeting Austin, TX	10/03/06
Postmortem Pharmacokinetics – The Good, The Bad & The Ugly Workshop SOFT Annual Meeting Austin, TX	10/03/06
Training on Horizontal Gaze Nystagmus (HGN) and Toxicology Governor’s Traffic Safety Committee Nassau County District Attorney’s Office Mineola, NY	7/31/06
Post Mortem Interpretation Workshop SOFT Annual Meeting	10/18/05
Oral Fluids-Research and Application Workshop SOFT Annual Meeting	10/18/05
Receptor Site Theory & Drug Interactions Workshop SOFT Annual Meeting	10/17/05
Interpretive Pharmacogenomics and Proteomics In Forensic Toxicology Workshop SOFT Annual Meeting	10/17/05
NLCP Inspectors' Training SOFT Annual Meeting	10/16/05
Forensic Toxicology Review Sponsored by SOFT Albany, NY	9/13-14/05
NYS Department of Health Recertification for Breath Analysis Operator Pomona, NY	12/08/04
Forensic Aspects of Alcohol Seminar A.W. Jones, Ph.D., DSc NYU Medical Center New York, NY	12/06/04
Advanced Mass Spectrometry Theory and Interpretation FBI Laboratory Symposium Washington, DC	8/30/04
New and Unique Technologies for Forensic Toxicology Laboratories FBI Laboratory Symposium	8/29/04

Washington, DC	
Statistics and Method Validation FBI Laboratory Symposium Washington, DC	8/29/04
NLCP Inspectors' Training SOFT Annual Meeting	8/28/04
Feeling Blue? Antidepressant Workshop Workshop, SOFT Annual Meeting	10/21/03
Practical Applications for LCMS in Routine Toxicology Workshop, SOFT Annual Meeting	10/20/03
Forensic Toxicology of Metals Workshop, SOFT Annual Meeting	10/20/03
NLCP Inspectors' Training SOFT Annual Meeting	10/19/03
Pharmacology and Toxicology of Brain Drugs Workshop, SOFT Annual Meeting	10/14/02
DUID, Research to Court Workshop, SOFT Annual Meeting	10/13/02
NLCP Inspectors' Training SOFT Annual Meeting	10/12/02
NLCP Inspectors' Training SOFT Annual Meeting	10/05/01
Ethanol Seminar, SOFT Annual Meeting	10/01/01
Urine Testing and Human Performance Seminar, SOFT Annual Meeting	9/30/01
Herbal Medicine Seminar, SOFT Annual Meeting	9/30/01
The Effects of Alcohol and Drugs on Human Performance and Behavior: 1999 Forensic Toxicology Seminar, NYS-Police Academy, Albany, NY	7/20-23/99
Pharmacology Reviews: Selected New Drugs: SOFT Annual Meeting	10/10/99
Drugs, Driving and Traffic Safety: Update: SOFT Annual Meeting	10/11/99
Practical Aspects of CI/MS for Drugs of Abuse Workshop: SOFT Annual Meeting	10/5/98
Rohypnol Detection Workshop: SOFT Annual Meeting	10/5/98

Operator Training for the Datamaster Model K Breath Alcohol Testing Instrument: National Patent Analytical Systems, Inc., Valhalla, NY	2/18-19/1998
Operator Training for the Draeger Alcotest 7110 MK III Breath Alcohol Testing Instrument, Draeger Instruments Corp., Valhalla, NY	1/22/98
"Forensic Toxicology Teleconference, James Garriott speaker: Sponsored by AACC	2/3/98
Operator Training for the Draeger Alcotest 7110 MK III Breath Alcohol Testing Instrument: New York State Police, Washington Hollow, NY	5/97
Training for the Draeger Alcotest 7110 MK III Breath Alcohol Testing Instrument: WC District Attorney's Office, White Plains, NY	1997
Illicit Production of Cocaine: AAFS Annual Meeting	2/18/97
Looking Forward & Backward: Three Decades of Toxicological Analyses: AAFS Annual Meeting New York, NY	2/18/97
Uppers and Downers: AAFS Annual Meeting	2/18/97
ASCLD/LAB Inspector Training Course: Albany, NY	11/23-25/97
Fundamentals of Medical Examiner Toxicology: SOFT Annual Meeting	10/96
Use of LIMS in a Forensic Laboratory: SOFT Annual Meeting	10/96
Drugs and Driving: Current Pharmacologic Issues (NHTSA): SOFT Annual Meeting	10/95
Advanced Forensic Toxicology: Pharmacologic Interpretative Issues (NHTSA): SOFT Annual Meeting	10/95
Conference on Drug Testing in Hair: SOFT Annual Meeting	10/94
Human Performance Testing Drugs and Driving Impairment: SOFT Annual Meeting	10/94
Legal Aspects of Urine, Blood, and Hair Testing: SOFT Annual Meeting	10/94
Statistical Approaches to Accuracy in Toxicology: AAFS Annual Meeting San Antonio, TX	2/94
Fundamentals in Forensic Toxicology: Pharmacologic Concepts	2/94
Inspector Training for SAMSHA Laboratories: HHS National Laboratory Certification Program VA	4/93
Human Performance- Drugs and Driving: SOFT/CAT Annual Meeting	10/93
GC/MS Workshop: SOFT/CAT Annual Meeting	10/93
Toxicology and Highway Safety Meeting, NYSP Crime Lab	1/93
Surviving the 90's: How to Manage Your Laboratory to Meet the New Federal Regulations Ciba Corning Saddle Brook, NJ	5/21/91

COMMITTEE

AAFS Awards and Scholarship Committee
American Academy of Forensic Sciences
2019-2021

Impaired Driving Advisory Council
New York State 12/2014

SWGTOX Group (Scientific Working Group – Toxicology)
Sponsored by Senator Lehey
February 2010 to 2014

ABFT Board of Directors
July 1, 2008 – June 30, 2017

ABFT Nomination Committee
2006-2007

MEETINGS

SOFT Annual Meeting (2020)
Virtual/Several Days

SOFT Annual Meeting (2019)
San Antonio, TX

AAFS Annual Meeting (2019)
Baltimore, MD

SOFT Annual Meeting (2018)
Minneapolis, MN

SOFT/TIAFT Annual Meeting (2017 – postponed until 1/7/2018)
Boca Raton, FL

SOFT Annual Meeting (2016)
Dallas, TX

SOFT Annual Meeting (2015)
Atlanta, GA

SOFT Annual Meeting (2014)
Grand Rapids, MI

SOFT Annual Meeting (2013)
Orlando, FL

NEAFS Annual Meeting (2012)
Saratoga Springs, NY

SOFT Annual Meeting (2012)
Boston, MA

SOFT Annual Meeting (2011)

San Francisco, CA

SOFT Annual Meeting (2010)
Richmond, VA

AAFS Annual Meeting (2010)
Seattle, WA

SOFT Annual Meeting (2009)
Oklahoma City, OK

SOFT Annual Meeting (2008)
Phoenix, AZ

SOFT Annual Meeting (2007)
Durham, NC

SOFT Annual Meeting (2006)
Austin, TX

SOFT Annual Meeting (2005)
Nashville, TN

FBI/SOFT/TIAFT Annual Meeting (2004)
Washington, DC

SOFT Annual Meeting (2003)
Portland, Oregon

SOFT Annual Meeting (2002)
Detroit, Michigan

SOFT Annual Meeting (2001)
New Orleans, LA

SOFT Annual Meeting (1999)
Puerto Rico

SOFT Annual Meeting (1998)
Albuquerque, NM

AAFS Annual Meeting
New York, NY (1997)

SOFT Annual Meeting (1996)
Denver, CO

SOFT Annual Meeting (1995)
Baltimore, MD

SOFT/TIAFT Annual Meeting (1994)
Tampa, FL

AAFS Annual Meeting (1994)
San Antonio, TX

Eighth International LIMS Conference (6/94)
Pittsburgh, Pa.

STOP DWI Law Enforcement Conference (4/94)

SOFT/CAT Annual Meeting (1993)
Phoenix, AZ

AACC Annual Meeting (1993)

SOFT Annual Meeting (1992)
Cromwell, CT

AACC Annual Meeting (1991)
Washington, DC

SOFT Annual Meeting (1991)
Montreal, Canada

SOFT Annual Meeting (1990)
Melville, NY

AACC Annual Meeting (1990)
San Francisco, CA

Meetings prior to 1990, not listed

Addendum 2



STATE OF NEW YORK
OFFICE OF THE INSPECTOR GENERAL
OFFICE OF THE WELFARE INSPECTOR GENERAL
OFFICE OF THE WORKERS' COMPENSATION FRAUD INSPECTOR GENERAL

EMPIRE STATE PLAZA
AGENCY BLDG. 2, 16TH FLOOR
ALBANY, NEW YORK 12223
(518) 474-1010

61 BROADWAY, SUITE 2100
NEW YORK, NEW YORK 10006
(212) 635-3150

65 COURT STREET, 5TH FLOOR
BUFFALO, NEW YORK 14202
(716) 847-7118

LETIZIA TAGLIAFIERRO
INSPECTOR GENERAL


November 5, 2019

Anthony J. Annucci, Esq.
Commissioner
New York State Department of Corrections
and Community Supervision
The Harriman State Office Campus
1220 Washington Ave
Albany, New York 12226

Dear Commissioner Annucci:

As you know, the Inspector General's Office is conducting a review of DOCCS's current utilization of assay kits for inmate drug testing. While this review is ongoing, and to ensure the integrity of the drug testing process, DOCCS must verify any positive test results from immunoassays of any kind through a laboratory independent from Thermo Fisher/Microgenics before any disciplinary or other adverse action is taken.

Sincerely,


Letizia Tagliaferro
Inspector General



STATE OF NEW YORK
OFFICE OF THE INSPECTOR GENERAL
OFFICE OF THE WELFARE INSPECTOR GENERAL
OFFICE OF THE WORKERS' COMPENSATION FRAUD INSPECTOR GENERAL

EMPIRE STATE PLAZA
AGENCY BLDG. 2, 16TH FLOOR
ALBANY, NEW YORK 12223
(518) 474-1010

61 BROADWAY, SUITE 2100
NEW YORK, NEW YORK 10006
(212) 635-3150

65 COURT STREET, 5TH FLOOR
BUFFALO, NEW YORK 14202
(716) 847-7118

LETIZIA TAGLIAFIERRO
INSPECTOR GENERAL

December 31, 2019

VIA HAND DELIVERY

Anthony J. Annucci, Esq.
Acting Commissioner
New York State Department of Corrections
and Community Supervision
The Harriman State Office Campus
1220 Washington Avenue
Albany, New York 12226

Case: NYS IG 2764-316-2019

Dear Acting Commissioner Annucci:

As you know, the Office of the New York State Inspector General is investigating the New York State Department of Corrections and Community Supervision's (DOCCS) inmate drug testing program, including its current contract with Thermo Fisher/Microgenics. Recently, pursuant to my November 5, 2019 correspondence, DOCCS began submitting positive test results that were obtained using Thermo Fisher/Microgenics testing equipment and procedures to an independent laboratory for verification purposes.

On December 19, 2019, based on preliminary information gathered by my office, I advised DOCCS to consider releasing any inmate who was serving a Special Housing Unit (SHU) or keeplock sanction as a consequence of a positive test for synthetic cannabinoids prior to November 5, 2019. According to DOCCS, this recommendation resulted in one inmate being released from SHU.

On December 30, 2019, my office learned that DOCCS submitted to Alere Toxicology/Abbott samples from 15 inmates who had initially tested positive for synthetic cannabinoids using the Thermo Fisher benchtop analyzer and procedures. According to the Alere results, all 15 samples were in fact negative for synthetic cannabinoids.

Based on these results, it is imperative that DOCCS undertake an immediate review of the records of any inmate who tested positive for synthetic cannabinoids since the installation of the Thermo Fisher benchtop analyzers at each New York State correctional facility. As part of this review, in an abundance of caution, I strongly advise DOCCS to consider reversing the disciplinary dispositions, expunging the records, and restoring the privileges of those inmates who tested positive for synthetic cannabinoids without an independent positive confirmatory test result.

Sincerely,

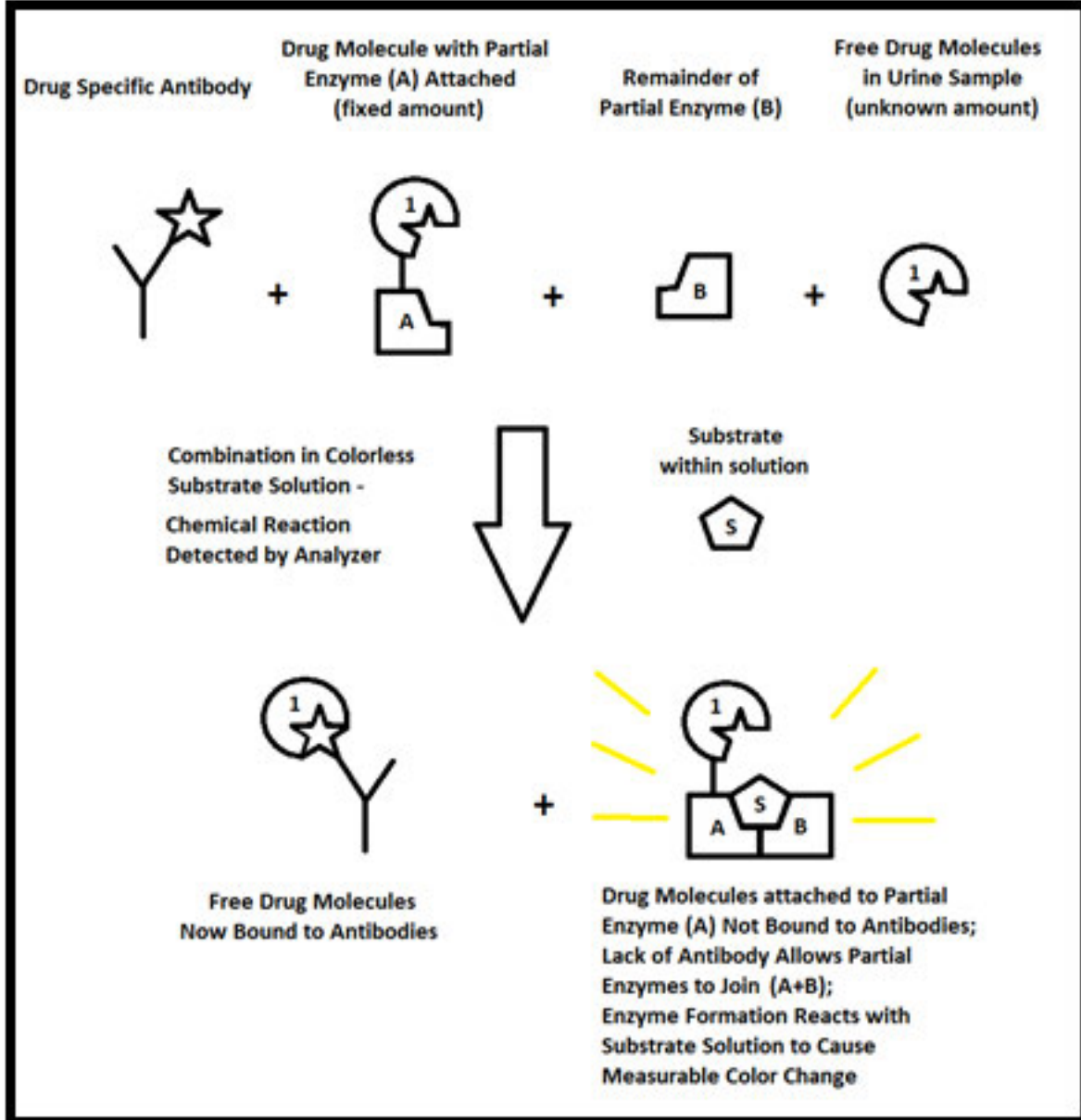


Letizia Tagliaferro
Inspector General

Enc.: Letter of November 5, 2019

Addendum 3

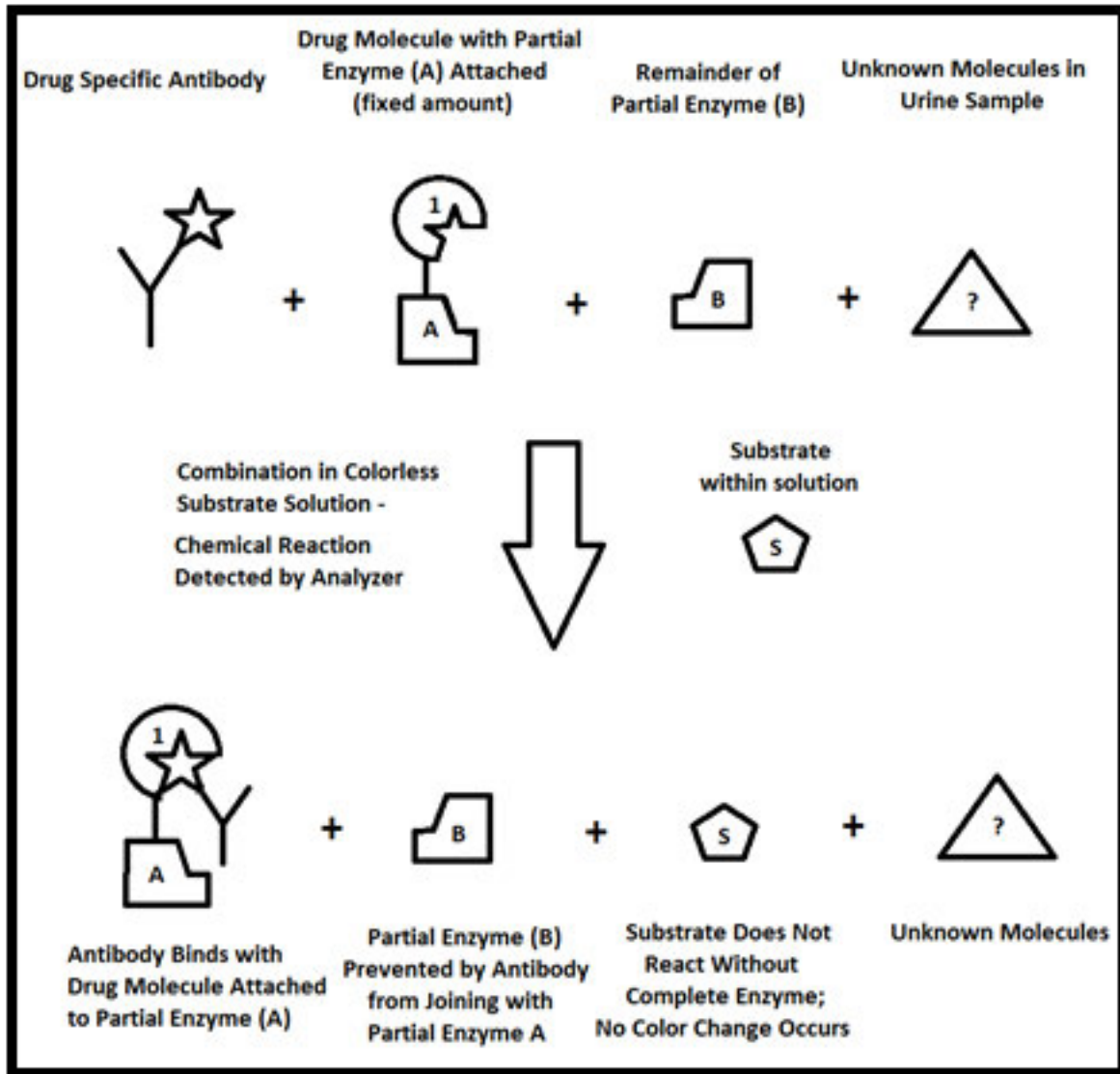
CEDIA-like Positive Result Due to Presence of Target Drug Molecules



As illustrated above, the immunoassay does not measure the free drug in the sample, but rather measures the color change caused by the known amount of drug molecules that did not bind with antibodies to complete the reaction. The strength of this reaction—the color change—is then measured.

Conversely, when the target drug being tested for is not found in the urine sample, the following illustration shows what occurs:

CEDIA-like Negative Result Due to Absence of Target Drug Molecules

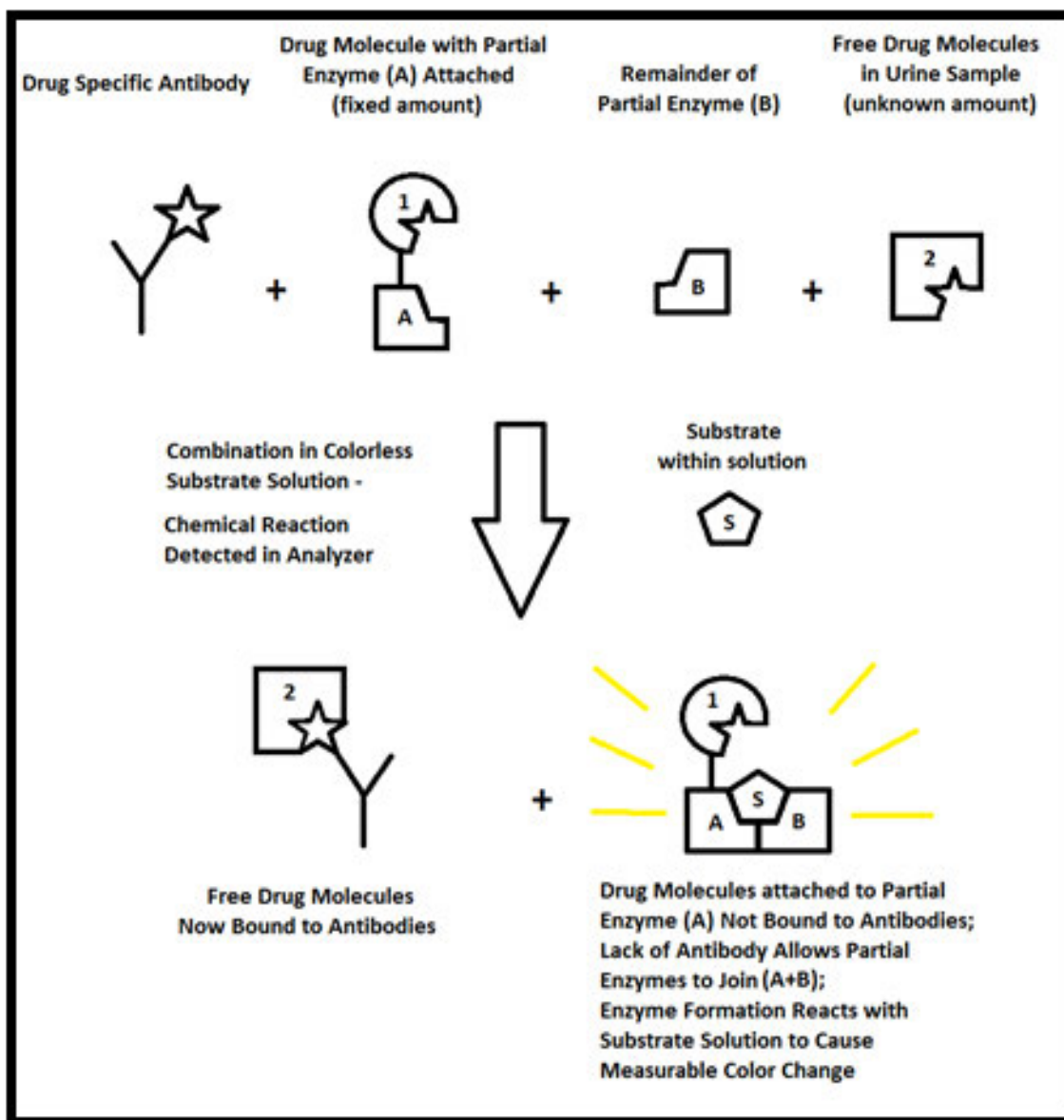


Immunoassay Cross-reactivity

Cross-reactivity occurs when molecules from a substance other than the drug being tested for bind with antibodies in a sample. Although antibodies are drug and/or drug-class specific and will generally bind with the target drug molecules, other factors may cause antibodies to bind with other substances. One such factor is that the chemical structure of a different substance so closely resembles the target drug molecule's chemical structure that the antibodies instead bind to the other substance's molecules.

The following illustration shows a cross-reactive immunoassay result.

CEDIA-like Positive Result Due to Cross-Reactivity



In this instance, the immunoassay will still cause a color change although the antibodies have attached to a substance other than the target drug. Such cross-reactivity may cause a false positive test result even though the target drug is not present. Given the potential for cross-reactivity, the DRI and CEDIA immunoassays only provide an indication that a sample may contain target drug molecules.

Cross-reactivity in immunoassays that test for drugs of abuse may both increase the sensitivity of the test and result in false positives. For example, buprenorphine, the primary component in the commonly used drugs Subutex and Suboxone, quickly breaks down in the body into three metabolites before being excreted in urine. An immunoassay that can test for buprenorphine and cross-react with each of the three metabolites will provide a greater indication that the urine contains buprenorphine. However, if a urine sample contains a substance, like an over-the-counter medication, with a structurally similar chemical composition to buprenorphine or its three component metabolites, cross-reactivity could occur and cause a false positive test result.