EXECUTIVE SUMMARY

For several decades the William A. Hinton State Laboratory Institute (Hinton Lab) has operated one of the three Forensic Drug Laboratories within the Commonwealth (the other two were operated by public safety entities). A longtime chemist within the Forensic Drug Lab (Drug Lab), Annie Dookhan (Dookhan), has recently acknowledged malfeasance with regard to the handling of an unknown number of drug analysis cases. The Attorney General and Executive Office of Public Safety and Security (EOPSS) are conducting an ongoing investigation, which led to closure of the Drug Lab on Thursday August 30, 2012.

In June 2011, Dookhan violated laboratory protocols and forged documentation regarding the chain of custody of 90 drug samples, all stemming from Norfolk County. Documentation irregularities were identified quickly and Dookhan (who denied any wrongdoing) was removed from testing duties. In December 2011, the MDPH Commissioner's Office learned of these events and directed Deputy General Counsel Steve Chilian (Chilian), to conduct a focused investigation of the incident. The investigation was conducted from December 2011 to February 2012, and found that evidence suggested Dookhan had in fact breached documentation protocols. Lab staff asserted that they had no questions concerning the quality and accuracy of Dookhan's work. Chilian was not asked to independently assess the accuracy of the pertinent test results. Based upon these findings, the Department began the process of terminating the employment of Dookhan. Beginning in late January 2012, MDPH, EOHHS, and the Governor's Legal Office notified the Norfolk County District Attorney, the District of Massachusetts U.S. Attorney, and other pertinent stakeholders of the 90 cases in which documentation was inappropriate. On March 9, 2012, Dookhan resigned from MDPH and the parties agreed to a neutral separation in lieu of a protracted termination process.

In July 2012, the MDPH Forensic Drug Laboratory was transferred to the Executive Office of Public Safety and Security, which together with the Attorney General, conducted a thorough investigation of Dookhan's work. Numerous additional alleged wrongdoings were identified through this investigation. In light of these findings, MDPH has conducted a comprehensive internal analysis of the policies, procedures, leadership, and infrastructure at the Forensic Drug Lab that surrounded these events. MDPH identified key potential root causes and steps that could have been taken to prevent malfeasance, notification of protocol breaches, quality assurance, and quality control processes, as well as compliance with national standards and guidelines.

The following report details these findings and describes key operational elements of the Drug Laboratory as it operated under MDPH oversight and control.

THE HINTON STATE LABORATORY INSTITUTE

Background

The William A. Hinton State Laboratory Institute (Hinton Lab) principally houses two bureaus within the Department of Public Health (MDPH), whose missions are disease prevention and surveillance in Massachusetts, the Bureaus of Laboratory Sciences and of Infectious Disease Prevention and Response. Additionally, the Hinton Lab encompasses elements of the MDPH's Drug Control and Food Protection Programs, the State Racing Commission Laboratory (Office of Consumer Affairs and Business Regulation), the New England Newborn Screening Program (operated for MDPH by University of Massachusetts Medical School), the National Laboratory Training Program, and the University of

Massachusetts Biologics Laboratories.

The Bureau of Laboratory Sciences (Bureau) provides high quality testing services, facilitates training of laboratory personnel in new testing technologies, promptly investigates and identifies emerging disease outbreaks, and provides expertise to public and private organizations to improve health status. A nationwide system of state-based laboratories complements the clinical laboratory services included in clinical practice and supports prompt diagnosis of diseases, whether of epidemic proportion or rare disease events. The Bureau is critical to identifying new and emerging problems through disease surveillance and control.

The Bureau is under the supervision of Dr. Linda Han (Bureau Director since June 2010) and is composed of 17 laboratories (prior to the FY13 transfer of the Forensic Drug Laboratory this number was 18) organized in four divisions: Analytical Chemistry, Molecular Diagnostics and Virology, Microbiology, and Central Services.[1] In the last decade MDPH has faced challenges in recruitment and retention of a Bureau Director of Laboratory Sciences because of the limitations on salary levels and the breadth of professional expertise required to oversee the diverse and continually evolving work. In recent years, the Hinton Laboratory has responded to issues as varied as the H1N1 influenza outbreak, mosquito-borne illnesses such as Eastern Equine Encephalitis and West Nile Virus, food-borne illness outbreaks, lead paint poisoning among children and the many demands related to threat of bioterrorism particularly after September 11. In the last six years, there have been three Laboratory Sciences Bureau Directors. One Bureau Director was identified after a lengthy national search, and two of whom were long-term MDPH employees who agreed to assume the role with reluctance (including Han).

Until recently, pursuant to M.G.L. c.111, §12-13, the MDPH was required, upon request from law enforcement authorities, to perform chemical analyses of drugs. Encompassing one of three laboratories in the Commonwealth assessing seized drugs, the Analytical Chemistry Division's Forensic Drug Laboratory (Drug Lab) was responsible for a large proportion of seized drug analyses requested by local and state police as well as federal law enforcement agencies operating in Massachusetts. From January 2003 until assumption of responsibility by the Executive Office of Public Safety, State Police Crime Laboratory/Forensic Services Group (FSG) at the beginning of fiscal year 2013 pursuant to Chapter 139 of the Acts of 2012, the MDPH conducted 355,276 analyses of seized drugs, averaging over 37,000 each year.

MDPH Standards of Practice as Compared with National Forensic Lab Guidelines

Policies and procedures in the forensic drug lab were developed from the recommendations of the *Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG). SWGDRUG* standards provide minimum guidelines offering direction to the development of forensic laboratory policies and procedures, but lack specificity in expected action steps. *SWGDRUG* guidelines were most recently updated in July 2011. Even if the Forensic Drug Lab fully complied with the *SWGDRUG* guidelines, these guidelines were vague and inadequate for guaranteeing the type of integrity needed to deliver high quality forensic drug analyses.

MDPH Standard Operating Procedures (SOPs) for the Forensic Drug Lab were most recently revised in 2004, and are consistent with the generalized guidance of *SWGDRUG* methods of analysis and drug identification.[2] MDPH SOPs do not include comprehensive quality assurance and quality control policies and procedures as recommended in the updated (2011) *SWGDRUG* guidelines. Julie Nassif, Division Director of Analytical Chemistry (Nassif) and Han report that routine quality control

[1] See appended organizational chart current in June 2011
[2] See appended MDPH Forensic Lab Standard Operating Procedures

mechanisms were in-place at the Lab, including performance of test controls, maintenance of reagent preparation records and processes to eliminate expired products, regimented standardization, calibration, and maintenance of equipment, and maintenance of workflow logs, and review of a variety of other test-related documents and records. There has no process for routine review and revision of the 2004 SOPs nor periodic written documentation of compliance.

As consistent with a component of the *SWGDRUG* educational standards, extensive initial training was provided to all chemists as a prerequisite to testing. Training was based upon SOPs and included all aspects of workflow, including bench tests, instrument analyses, and documentation, and technician competency was documented by supervisor observation and proficiency testing via blinded analysis of previously tested samples.

There are varying acceptable national standards to guide the work of forensic laboratories. EOPSS is in the process of attaining International Organization for Standardization (ISO) accreditation, which has training, personnel, equipment and instrumentation requirements that exceed those of *SWGDRUG*. These accreditation requirements also include a series of Quality Manual and Management System policies and procedures and substantial informatics system enhancements associated with meeting the ISO standards in order to capture more detailed data on testing, technician activities, reagents used, equipment maintenance, as well as additional information technology systems specific for document management and control. There are also significant expenses associated with the accreditation process itself, with enrollment in suitable proficiency testing programs applicable to laboratory testing activities, and with instrument calibration, maintenance, and replacement. MDPH did not have the resources to support these significant investments and this contributed to the decision to pursue EOPSS to transition the Forensic Drug Laboratory to public safety.

Prior to 2007, a Bureau-wide quality assurance and quality control (QA/QC) unit staffed by three full-time employees who provided targeted oversight of quality programming for the 18 laboratories. QA/QC processes included review of laboratory SOPs and compliance documents: Each laboratory appointed representatives to participate in unit activities. Due to significant budgetary restrictions in fiscal year 2008, the Bureau eliminated the centralized QA/QC function, instead decentralizing quality control data reviews to laboratory technical supervisors at the division level. Division Directors received ongoing monthly reports on QA/QC concerns and submitted reports through the chain of command for review and approval by the Bureau Director. Documentation redundancies were developed to ensure that potential gaps would be identified, including parallel paper-based and computerized log-books. Elements of this QA/QC system pertaining to chain of custody led to early identification of issues surrounding the Dookhan case.

The core functions of a forensic laboratory are distinctive from those of a traditional public health laboratory, where the focus is on surveillance and direct intervention to ensure individual and population health. For example, the Forensic Drug Lab requires technical expertise in standards of chain of custody and criminal law. In addition, unlike the traditional public health facilities at the Hinton Lab, there was no outside organizational oversight of QA/QC practices in the Forensic Drug Lab beyond that provided through accreditation processes. As noted elsewhere in this report, the forensic drug laboratories overseen by EOPS have begun the process of seeking specialized drug laboratory external certification but the MDPH forensic laboratory lacked the resources to fulfill this standard.

Testing Protocols

As specified within the *SWGDRUG* standards, there are three testing methods categories commonly used in the Forensic Lab for analyses of specimens, with workflow designed to include preliminary and confirmatory identification.

Category B and C tests provide the initial (*Primary*) test in the Drug Lab workflow. These include color tests, microcrystalline analyses, and ultraviolet visualization. They have only moderate discriminatory power, and are not associated with data that can be memorialized with a instrument-generated paper or computer trail and reviewed. These simple bench top tests have no associated documentation beyond a chemists' findings. Documentation of Category C tests includes a reviewable work card, but accuracy can only be directly confirmed through repeating the test.

Category A tests utilize sophisticated instrumentation such as Mass Spectrometry, Infrared Spectroscopy, and Gas Chromatography, have high discriminatory power, and are used as confirmatory tests. They produce instrument-generated documentation of test results that may be reviewed by a second chemist or a lab supervisor to further ensure accuracy.

Forensic Laboratory Workflow [3]

Seized drugs for testing arrived at the Forensic Drug Lab contained in sealed and initialed evidence bags delivered through a chain of custody transfer from a law enforcement officer to an Evidence Officer (EO) at the Lab. The EO weighed the evidence bag with contents and recorded its gross weight on an evidence receipt. The EO then assigned an evidence control number to the sample evidence bag, and recorded the control number on the evidence receipt. Sample evidence bags were placed in a bar-coded manila envelope (Evidence Envelope) for processing and stored in the Evidence Room (safe). An evidence receipt was provided to law enforcement officer. By protocol, the Evidence Room was to be locked at all times with access by a key or palm reader – both EOs and chemists had access to the Evidence Room, although by protocol, access was to be restricted when EOs were not present. The Evidence Room was secured and alarmed at close of business and per Nassif, override codes were not provided to chemists.

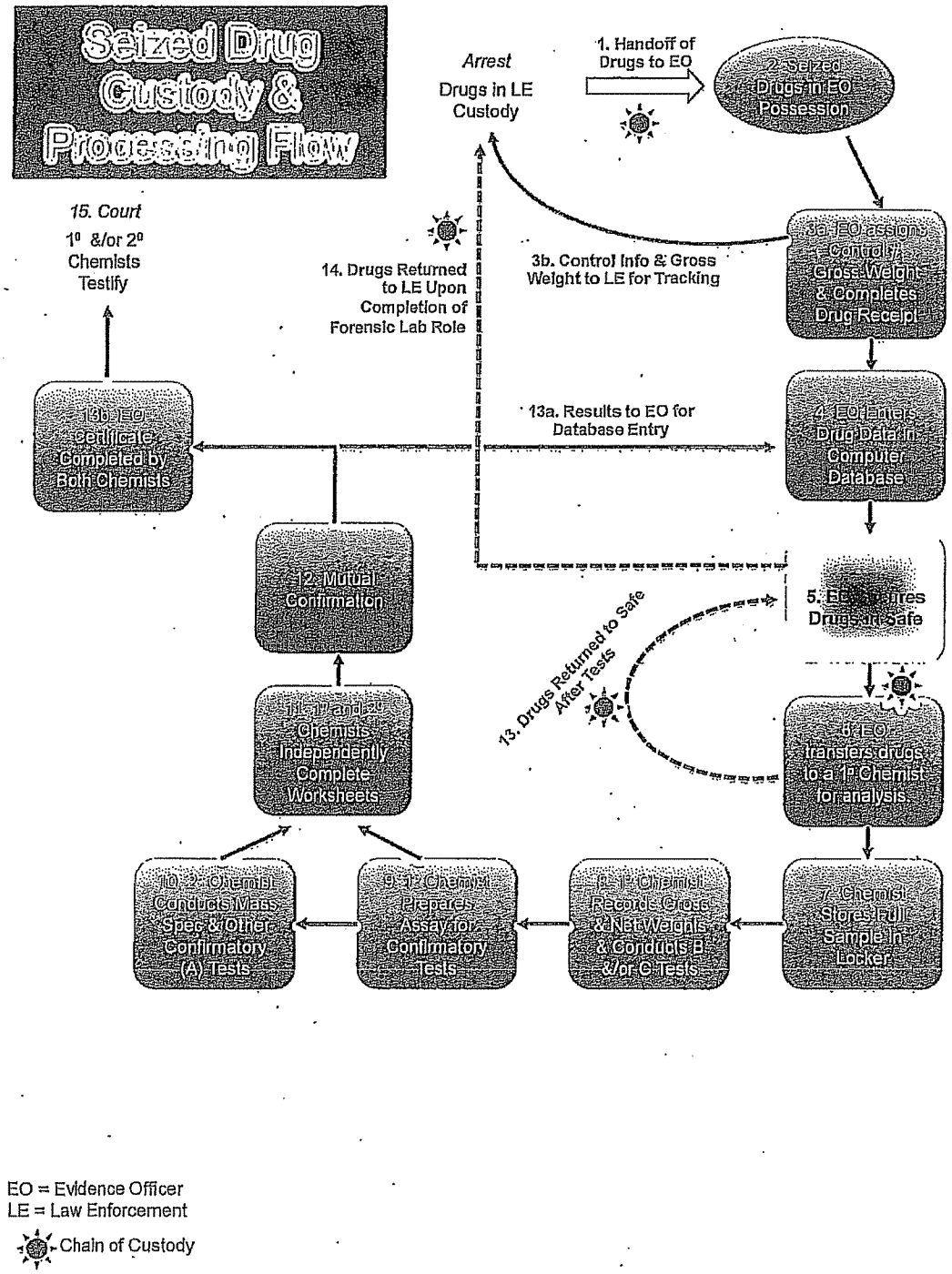
Upon submission of a sample, an EO completed a Control Card and transferred duplicate data to a redundant computerized database for tracking samples throughout the testing process. The control card was placed in the Evidence Envelope and immediately placed into the evidence safe until assigned for testing. Testing assignments were made by the EOs. All assignment information was entered into the computerized database with the name of the assigned chemist and at which time the chemists were notified to pick up samples.

The EO was required to record his/her initials and the date of the transfer. The person receiving the sample was required in the presence of the Evidence Officer to record his/her initials thereby signifying receipt. Transfer of custody of samples required both physical handoff as well as computer entry by the EO – the computerized database was password protected, and chemists were not granted access.

The chemist assigned a sample for testing was defined as the *Primary*. That individual was responsible for conducting Category C analyses, as well as for preparing samples for confirmatory Category A tests. The *Primary* completed the Drug Powder Analysis Form (*Powder Sheet*) which included the samples' control number, the requesting agency, the initials of the analyst performing the test, the number of samples, a physical description of the sample, its gross and net weights, the number and types of test(s)

[3] See attached annotated floor plan of the Forensic Drug Lab. *(included at the end of this document for now)*

performed, the test results and the dates of testing. The prepared Category A sample specimens (prepared vials) were transferred to the confirmation (*Secondary*) chemist with the Drug Lab/Mass Spectrometry Control Sheet documenting the transfer.



The *Secondary* chemist completed the confirmatory test, filled out the Control Sheet and returned it to the primary chemist for mutual confirmation, in which the two chemists conferred to ensure aligned results. The *Primary* placed both the Powder and Control Sheets in the evidence envelope and returned

the complete sample to the Evidence Officer for storage in the Lab safe. Chemists controlled the full evidence sample during the entire testing process. Each chemist had his or her own locker (47"x20"x28") to hold evidence envelopes during the testing process. Chemists received trays with multiple evidence envelopes for testing – the number of samples allocated on a daily basis varied among chemists. The EO entered final results into the computer database and prepared a certificate for notarized signature by the both chemists. Pursuant to the U.S. Supreme Court decision in *Melendez-Diaz v. Massachusetts* in 2009, the *Primary* chemist was often called upon as a witness upon introduction of a certificate of analysis as material evidence.

CHRONOLOGY AND NARRATIVE OF KEY EVENTS

Annie Dookhan Employment History

Dookhan was first hired in November 2003 by the MDPH/Hinton State Laboratory Institute as a Chemist 1 in the Forensic Drug Lab. Dookhan reported to Chuck Salemi (Salemi) who was the Lab Supervisor for the Drug Lab for the duration of Dookhan's employment with the MDPH (November 2003 – March 2012). In 2005, Dookhan was re-classified from a Chemist 1 to Chemist 2 based on her successful performance up until that point in time.[4] As a Chemist 2, the workload and tests Dookhan conducted involved increasingly complex drug cases. Throughout her employment, Dookhan was considered a high performer by her supervisors and a valuable asset to the team. As the Drug Lab continued to experience significant back-logs due to budget reductions, Dookhan's supervisor often acknowledged what was described as a strong work ethic and drive to test samples were welcomed by her supervisors.

A review of the volume of sample assignment by chemists shows that between 2004 and 2011, Dookhan was consistently assigned (and presumably tested) more samples at the drug lab than any other chemist, exceeding her peers by as much as 50% more than as the second highest chemist.[5]

Timeline and Action Steps

In June 2011, Elizabeth O'Brien (O'Brien), Lab Supervisor I, and Shirley Sprague (Sprague), Evidence Officer, became aware of a potential breach in documentation protocols for processing drug samples.[6] On June 16, 2011, these staff discovered that transfers of approximately 90 samples from the evidence safe to the chemist who analyzed them (Dookhan) were not documented in accordance with the Drug Lab's SOPs. The discovery was made by Sprague while entering test results for samples into the computer database. As she entered results, the database indicated that the sample had not yet been assigned to a chemist. At that time, Sprague examined the physical log book and determined that there was no indication of a chain of custody transfer for these samples. Sprague's supervisor, O'Brien, confirmed her findings and notified Nassif of the breach. O'Brien, Nassif, and Salemi subsequently met as a group to determine next steps. No copy was made of the page from the physical log book that had missing initials/signatures. On June 20, what had previously been confirmed as blank entries in the log book were discovered to have been subsequently completed, documenting transfer of samples from

[4] Employee Performance Review Forms (EPRS) were only included in the personnel file for 2004-2007. Incomplete performance review documentation is unfortunately, not an unusual or unique situation.
Please refer to chart below displaying the testing trends of AD compared against 2nd highest chemist's test, total FTEs, total annual tests, and mean chemist testing patterns.

[6] Please refer to MDPH Investigation Summary, February 29, 2012, for specific details regarding witness statements and timeline of events from June 2011 breach.

Evidence Officer Gloria Phillips (Phillips) to Dookhan on June 14, 2011. A review of Phillips' time logs indicated that she was on leave on the day in question, and therefore, was not present to make corrective entries. O'Brien, Nassif, and Salemi confronted Dookhan on June 20 about the missing initials/signatures and then finding this information completed after that discovery. Dookhan denied falsifying entries to the log, though it remained the opinion of her supervisors and the Evidence Officer that Dookhan had both violated proper protocol for release of samples and retroactively falsified log entries.

Salemi and Nassif agreed that the best course of action involved removing Dookhan from testing duties and re-assigning her to desk duties effective June 21, 2011. Dookhan's physical workspace was moved outside the Forensic Drug Lab. According to Nassif, Dookhan's access to the Drug Lab was not immediately revoked. Dookhan's access to the Evidence Room was later restricted ***(DPH to confirm date w/Salemi)***.

In addition to reassigning her to work outside the laboratory, Salemi and Nassif changed Dookhan's reporting relationship from Salemi to the Division Director. Nassif met with Han about the situation within several days of discovering the breach in documentation. The breach and the re-assignment in duties and supervision were not reported to the EOHHS Human Resources. After internally reviewing the matter, Nassif and Salemi interpreted the irregularity as an isolated documentation failure, and concluded that the integrity of the test results was not compromised. Neither Nassif nor Han notified the Commissioner's Office, Office of the General Counsel, or EOHHS HR about the situation with Dookhan, and the test results were reported to the relevant enforcement authorities.

A total of 90 samples were identified as those that had been removed by Dookhan from the Evidence Room without proper protocol. All were from Norfolk County, including 84 from Quincy and six from Wellesley. Between the time of her removal from testing duties and departure from the MDPH, Dookhan did not testify in court on any of the cases involving these samples. She was summoned to appear at one case in Quincy (Hawker) on December 18, 2011, but the case did not go forward.[7]

During this same time period, MDPH began working directly with the Executive Office of Health and Human Services (EOHHS) and the Executive Office of Public Safety and Security (EOPSS) on a plan that would involve transferring the drug lab operations and personnel to EOPSS as of July 1, 2013 (FY13). It was during these planning meetings that EOHHS HR/Labor learned of issues with Dookhan from Nassif. As staff on the proposed transfer list were reviewed, Dookhan was identified as someone who would not be part of the transfer. Nassif shared information about the breach at that time, and the EOHHS HR/Labor staff immediately notified Monica Valdes Lupi (Valdes Lupi), MDPH Deputy Commissioner about the situation in early December 2011.

Nassif stated that the breach and re-assignment were not issues that she felt rose to the level of notifying HR/Labor or the Commissioner's Office. At the time of the incident, she felt that it was an isolated event with a high-achieving chemist who had been working too hard and experiencing a lot of personal challenges. In a separate interview, Han relayed that while she did not personally know Dookhan, she understood from Nassif that Dookhan was considered a valued employee who may have erred because she was performing a high volume of tests and spending much of her time at the lab.

Formal Investigation of Annie Dookhan in December 2011

[7] See appended summary of cases and pertinent discovery motions. MDPH is in process of verifying information regarding Dookhan's appearances in court.

Valdes Lupi notified MDPH Commissioner Auerbach about the breach and recommended that they launch a formal investigation recognizing the potentially significant impacts of the breach in protocols that occurred in the Lab. The Commissioner's Office assigned Steve Chilian (Chilian), Deputy General Counsel at the MDPH, to conduct the investigation solely on the allegation of whether the transfer of numerous samples from the evidence office to the lab for testing was properly assigned and recorded in accordance with drug lab protocols. By design, the investigation was focused on the documentation incident, with targeted interviewing of key staff and without a more extensive examination of policies and procedures within the Drug Lab or of the integrity of the QA/QC systems.

Key staff, including Han, Nassif, Salemi, O'Brien, and Dookhan were interviewed on December 21–22, 2011. Draft versions of the investigation report were reviewed in consultation with the Commissioner's Office, EOHHS HR, and other state attorneys over the next several weeks. Additionally, an outreach plan was submitted to EOHHS on January 13, 2012, which provided details regarding proposed communication with stakeholders. The outreach plan was finalized on or about February 15, 2012. A final version of the report was submitted to key staff in these offices on February 29, 2012 as appended.

The investigation conducted was focused on the specific question of sample transfer and documentation inconsistencies. At the time, this approach was taken because it was reported to the Commissioner's Office and Chilian that "the chemist had been conducting forensic drug analysis for over eight years and during that time had been a stellar, reliable employee with a reputation for diligent work, long hours and most significantly, the accurate and efficient analysis of samples. All the samples were tested and no samples were missing. This employee had recently experienced a terrible tragedy and personal loss, but there had been no problems with the accuracy and reliability of the samples she analyzed. Lab supervisors believed that the analysis of the samples, without following appropriate protocol, was imply a result of the chemist's desire to reduce the backlog of requests for testing. There was no question concerning any other motive."

The investigation's conclusions noted that "based upon a preponderance of the evidence collected during the course of this investigation through interviews and review of documentation, it can be concluded that Dookhan failed to follow Lab protocols for the transfer and documentation of samples for testing, and subsequently created a false record of said transfers." The investigation noted that Han and Nassif had not reported this incident to DPH Commissioner or General Counsel because they did not appreciate its potential legal significance and because of their opinion that the test results had not been affected. The conclusion of Lab leadership that the samples had been accurately tested was based upon a number of factors, including the standing and work history of Dookhan. The chemist had been conducting forensic drug analyses for the MDPH for more than eight years at that time, and had a reputation for diligent, accurate, and efficient work.

Notification of Legal Community

Beginning on January 31, 2012, the Governor's Legal Counsel notified Norfolk County District Attorney Michael Morrissey and the United States Attorney General Carmen Ortiz, as well as the Massachusetts District Attorneys Association. MDPH General Counsel followed up with the Norfolk County District Attorney's Office and the U.S. Attorney General's Office, Massachusetts District, and retests of samples were conducted when requested.

On February 1, 2012, recognizing the potential breadth of legal impact of the violations of chain of custody, Bureau leadership sent a letter to the Norfolk County District Attorney detailing the irregularities. The MDPH notified the Norfolk County District Attorney that there was no evidence that

the chain of custody infractions had an impact on the integrity of the samples or of the accuracy of the sample analysis.[8]

In early February 2012, MDPH General Counsel Donna Levin (Levin) communicated with Jean Marie Carroll, the Deputy District Attorney (Carroll) in the Norfolk DA's Office where the cases involving the 90 samples were at issue. Carroll indicated on February 14, 2012 that given the information relayed to her about the breach in protocol, Dookhan would not be called to testify in these cases or any cases in Norfolk County. Levin and Carroll discussed requests for retesting of samples for cases going to trial and retesting was done as requested. Levin also spoke with Attorney Jim Lang (Lang) in the United States District Attorney's Office about a federal case involving Dookhan but unrelated to the 90 samples. Lang requested retesting of pertinent samples, which was completed as bid.

Chilian advised Han and Nassif that Dookhan should not testify on the cases involving any of the 90 samples and to advise the Legal Office if she was subpoenaed. MDPH's understanding is that Dookhan did not testify in any of these cases. MDPH has reviewed a log of Dookhan's time spent in court on various cases unrelated to the 90 samples. However, this document does not indicate whether a given trial went forward or whether Dookhan testified. MDPH Office of the General Counsel is conferring with the AGO to determine if and when Dookhan has testified in any case since June 2011.

On February 21, 2012, Han sent a follow up letter to the Norfolk County District Attorney with additional details on the results of the investigation. The February 21 letter was disseminated to all County District Attorneys offices in the Commonwealth.

Departure of Dookhan

While the investigation report and outreach plan were being vetted, and upon confirmation that a significant breach of protocol by Dookhan occurred, the MDPH began proceedings to end her employment. Effective February 21, 2012, pending a Show Cause Hearing, the MDPH placed Dookhan on a paid administrative leave of absence. Dookhan's MOSES union attorney accompanied and consulted her in meetings with EOHHS HR/Labor regarding the terms of her resignation. Factoring in the desire to end Dookhan's employment in a timely way without a lengthy union challenge and her prior positive work record, MDPH agreed to a separation. In consultation among the Bureau, the Commissioner's Office, General Counsel and EOHHS HR/Labor, and in the interest of avoiding a prolonged termination process with uncertain outcome, the MDPH elected to accept Dookhan's resignation on March 8, 2012. The parties agreed to a separation agreement effective March 9, 2012.[9]

ROOT CAUSE AND GAPS ANALYSIS

On August 31, 2012, the MDPH convened a team of senior leaders from across the Secretariat and the Agency to complete a review of circumstances that surrounded the improprieties at the Drug Lab involving Dookhan.[10] This Team conducted interviews of key Bureau of Laboratory Sciences leadership, including Han, Nassif, and a former Acting Bureau Director (Dr. Alfred DeMaria). The Team reviewed policies and procedures and assessed compliance with optimal laboratory standards. The Team developed a comprehensive process mapping tool to understand key problems and vulnerabilities

[8] Please see letters to Norfolk County District Attorney Michael Morrissey attached, dated February 1 and February 21, 2012.

[9] Please refer to copy of settlement agreement in AD personnel file for terms/conditions, as well as her letter of resignation.

[10] Team members included: Commissioner John Auerbach; Deputy Commissioner Monica Valdes Lupi; General Counsel Donna Levin; Iyah Romm, Director of Policy and Strategic Planning, Bureau of Health Care Safety and Quality; James Montgomery-Hyde, EOHHS HR Director; Dr. Al DeMaria, Chief Medical Officer, Bureau of Infectious Disease Prevention and Response.

that may have contributed to unidentified irregularities. Additionally, the Team has developed an understanding of possible root causes and potential quality assurance and quality control gaps.

As stated above, the Forensic Drug Laboratory utilized the *SWGDRUG* standards to guide its work. However, while *SWGDRUG* provides some minimum generalized direction, it lacks specificity in expected action steps. For example, the standards require that protocols exist to insure the integrity and security of the evidential material but do not detail what policies, procedures, or protocols should include. Therefore, in considering the deficiencies of the forensic drug laboratory, our analysis includes both comparisons with *SWGDRUG* minimum standards, as well as a higher level of expectation of performance of the agency.

The Inherent Dangers within Laboratory Settings

Within the Forensic Drug Laboratory, as in many other laboratories, there are staff who work somewhat independently at the laboratory bench-top. Often without a supervisor within the immediate vicinity, staff are trusted to carry out a number of key tasks such as weighing drug samples, performing certain chemical tests, and describing the observable physical characteristics of a sample. There are safeguards that are put in place to limit the likelihood of malfeasance or poor quality work. These include: *1)* careful review by a supervisor of the required written documentation of essential sample characteristics by the chemist for each test performed, and *2)* periodic random re-testing of the chemists' results by a supervisor. At the Forensic Drug Laboratory, these measures and others were taken yet they failed to identify the alleged wrongdoing of Dookhan. These events demonstrate the damage that can potentially be done by a rogue employee who can maliciously manipulate the testing and documentation process to minimize the chance of discovery – as may well have been the case in this instance. Certain conditions t the Forensic Drug Laboratory might have enhanced this vulnerability. For example, there were numerous instances when chemists worked alone rather than as teams or side-by-side.

Systems and Infrastructure

In addition to the inherent vulnerabilities potentially associated with a skilled but rogue employee, it is also clear that there were weaknesses in the Forensic Drug Lab, which could and should have been addressed:

- **Insufficient Safeguards on Access to the Evidence Room and Safe:** In its initial investigation from December 2011 – February 2012, MDPH identified that insufficient standards were in place regarding access to drug samples. Prior to changes in protocol initiated subsequent to the Dookhan protocol breach, access to the Evidence Room was gained either through a keyed lock or through a palm reader. Chemists and Evidence Officers both had key and palm access. After close of business, an alarm in the Evidence Room was activated and only the Lab Supervisor and Division Director had the override codes. By policy, chemists were not allowed to enter the Evidence Room without an EO present. However, the palm reader system did not record a log of entries or a mechanism to flag inappropriate entrance. Upon investigation of Dookhan in June 2011, the Lab Supervisor (Salemi) noted that the Evidence Room keys he had provided to the chemists also opened the evidence safe. Upon discovery, Salemi replaced the lock to the evidence safe. Salemi noted at the time of his interview in December 2011 that he did not believe that chemists were aware that their keys also opened the safe.

In light of recent information regarding Dookhan's admission of malfeasance, it appears that she had access to areas of the lab without authorization, and she took samples without following the required documentation protocols.

- **Absence of Camera Surveillance:** The evidence regarding efficacy of surveillance cameras in the prevention of tampering is equivocal. Nonetheless, surveillance cameras may have been a tool to deter grossly inappropriate or negligent activities, including entering restricted space without authorization. However, cameras would have been less effective for ensuring that tests were being conducted appropriately at the bench. Surveillance cameras may be beneficial for retrospective review after identification of irregularities or potential malfeasance, and for monitoring activities of chemists and EOs who work after normal business hours. Several other laboratories at the Hinton facility have surveillance cameras often as a requirement of federal or laboratory accreditation. Examples include bioterrorism, viral isolation, and tuberculosis.

- **Absence of a Mechanism to Detect or Monitor Adverse and Poor Quality Events:** As a component of QA/QC, there must be a mechanism that detects unusual or unacceptable occurrences related to quality. One routine method of tracking such events in a laboratory setting is through the use of a discrepancy or adverse events log. A discrepancy in this setting refers to instances in which the results of two (or more) chemists are discordant. At the Drug Lab, samples inconclusive for reasons of discord are returned to the *Primary* chemist who is principally responsible for resolving the cause of the discrepancy. This process is referred to as a "return." Anecdotally, co-workers noted that there was an increase in the number of returns associated with Dookhan beginning in January 2011, but due to the lack of a centralized process for tracking these instances, this allegation cannot be confirmed.[11] Returns are an important indicator of a potential lapse in test quality, but the Drug Lab did not have a written mechanism in place to capture and monitor these data routinely. Unlike the Forensic Drug Lab, virtually all of the other 17 laboratories at the Hinton Lab maintained a form of discrepancy or adverse events log. Maintenance of such a log as well as ongoing tracking of volume of routine concerns or issues should have been a standard practice in the Forensic Drug Lab. *SWGDRUG* quality control and quality assurance standards require a process to identify and monitor such occurrences but do not specify a preferred method.

Management, Supervision, and Expertise

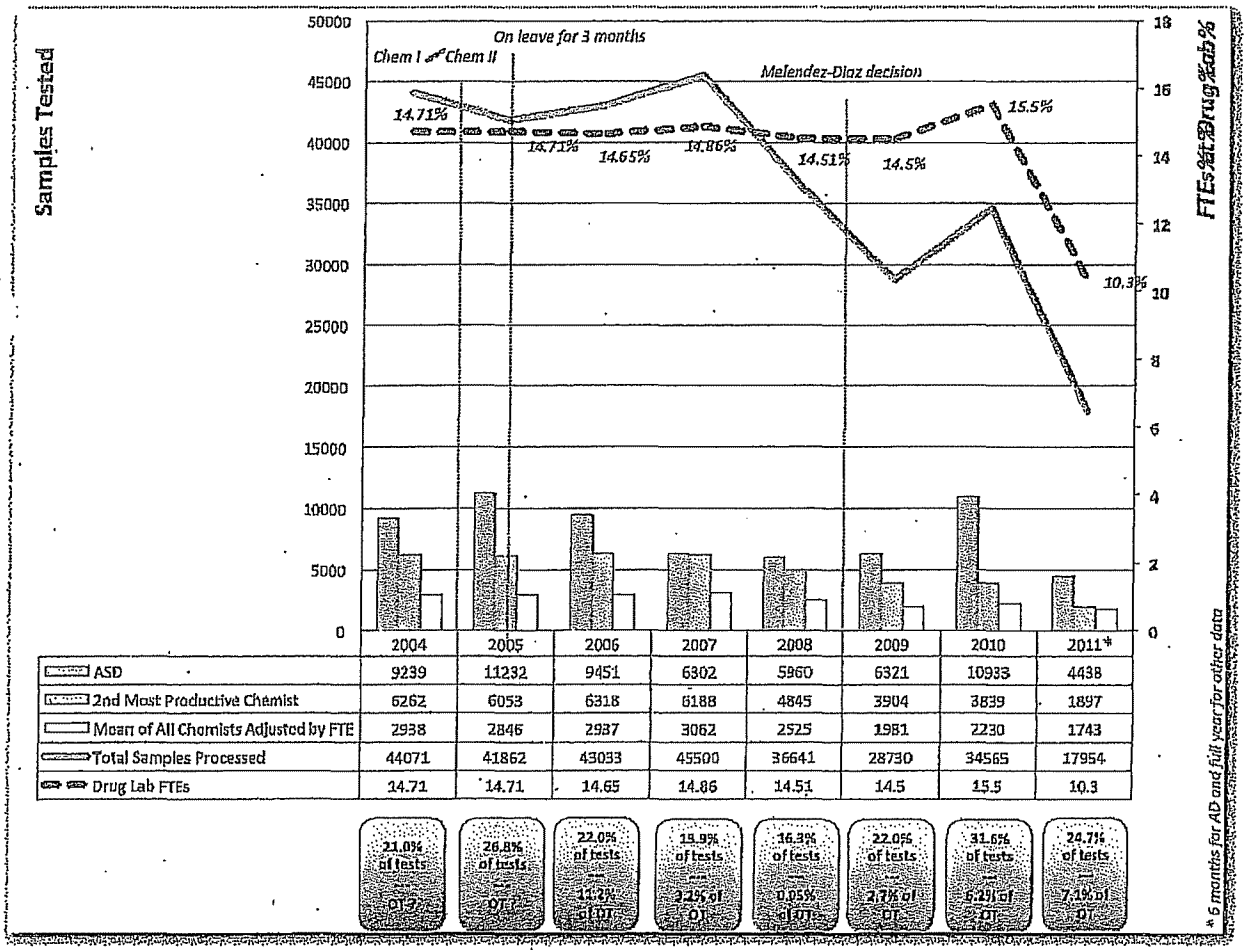
- **Lack of Close Supervision and Oversight:** While well trained in chemical analytic work and laboratory oversight, Nassif did not have experience with the Forensic Lab prior to the Lab's transfer to her Division. Nassif relied heavily on Salemi, the Drug Lab Supervisor, for subject matter expertise. Nassif met with Salemi on an *ad hoc* basis, not during regularly scheduled meetings. Initially Nassif chaired a monthly meeting of all Lab staff. Yet, after the *Melendez-Diaz* decision in 2009, Nassif reported that she found it increasingly difficult to meet with staff because of their increasing commitments requiring their participation in court proceedings.

  The lack of careful review and oversight is clearest with regard to the insufficient attention to Dookhan's unusually high volume of testing. From January 1, 2004, through December 31, 2011, Dookhan was assigned 25.3% of all analyses in the Drug Lab and completed 21.8% of all

[11] See memorandum attached to Major James M. Connolloy, FSG from Dr. Guy Vallaro, FSG dated July 19, 2012 in which Dr. Vallaro describes a series of conversations with Michael Lawler (Chemist 3), Peter Piro (Laboratory Supervisor 1), Ken Gagnon (Laboratory Supervisor 3), and Charles Salemi (Laboratory Supervisor 2) after assuming leadership of the Lab.

tests conducted by staff. The *Melendez-Diaz* decision in 2009 significantly hindered the overall volume of testing at the Lab because chemists spent more time in court. Despite the significant decrease in overall testing from 2008 to 2009 (a reduction of more than 16,000 samples), Dookhan's productivity remained relatively stable, decreasing by only 305 tests assigned. In 2008, Dookhan completed 16.3% of all tests in the Lab, 22.0% of the total in 2009, 31.6% of the total in 2010, as well as 24.7% of the annual total in 2011 despite only testing from January 1 to June 21. These indications should have prompted closer attention to her work.

During interviews on September 4, 2012, Valdes Lupi and Montgomery-Hyde were told by Nassif that there were concerns that Dookhan's productivity seemed unusually high. Nassif noted that as a result, Salemi conducted a limited audit of Dookhan's work *(date)*, which revealed no technical inconsistencies or other quality-related problems. Nassif reported that this audit consisted of repeating the primary and confirmatory tests for selected samples previously tested by Dookhan. MDPH and EOPSS are collaborating to identify written confirmation of this audit. No subsequent audits targeted Dookhan differentially from other chemists.



	2004	2005	2006	2007	2008	2009	2010	2011*
ASD	9239	11232	9451	6302	5960	6321	10933	4438
2nd Most Productive Chemist	6262	6053	6318	6188	4845	3904	3839	1897
Mean of All Chemists Adjusted by FTE	2938	2846	2937	3062	2525	1981	2230	1743
Total Samples Processed	44071	41862	43033	45500	36641	28730	34565	17954
Drug Lab FTEs	14.71	14.71	14.65	14.86	14.51	14.5	15.5	10.3

Dookhan's consistently high testing volumes should have been a clear indication that a more thorough analysis and review of her work was needed.

- **Lack of Specialized Quality Control Oversight:** In 2007, as resources decreased, the centralized Hinton Laboratory QA/QC oversight team was phased out. While at the time prioritizing the retention of front-line staff and assigning the quality control monitoring to each individual laboratory seemed the optimal decision, processes for ensuring quality and validity of

work were not sufficiently maintained in the Forensic Drug Laboratory. MDPH is in the process of locating and subsequently reviewing the oversight team's audits of the Drug Lab.

- **Poor Judgment Regarding the Response to the Violation of Mandated Protocols:** The June 2011 irregularities involving chain of custody should have been reported to the Commissioner's Office and the Office of the General Counsel immediately upon identification at the Forensic Drug Laboratory. Han acknowledges that she and Nassif did not recognize the significance of the breach and its impact on court cases. Han and Nassif received a cautionary letter in March 2012 disciplining them for this lack of disclosure, and were reprimanded for their failure to disclose the breach in a timely manner. Nassif was placed on administrative leave effective August 30, 2012.

  The DPH Central Office responded appropriately in December 2011, by conducting an investigation of the June breach, notifying the Norfolk County District Attorney's Office regarding the 90 cases and beginning the process to terminate Dookhan. However, the scope of its investigation was too narrow. A broader, more thorough investigation of the operations of the Forensic Laboratory was indicated. Had a more comprehensive investigation been conducted, the issues uncovered by the EOPSS/AGO investigation might have been detected earlier.

PROACTIVE REVIEW OF QA/QC IN OTHER HINTON LAB FUNCTIONS

In recognition of the need for proactive assessment of quality assurance and quality control practices throughout the Hinton Lab, the MDPH has engaged the services of the Association of Public Health Laboratories and the Centers for Diseases Control and Prevention to conduct a multi-day, on-site audit of all 17 remaining public health laboratories. In addition, most of the 17 laboratories are certified by federal oversight agencies, which regularly audit and assess the quality of their work. DPH will request that each of these oversight agencies return to the Hinton Lab to reassess the quality of services provided. These multiple external expert evaluations will include the review of policies, procedures, protocols and staffing ratios and will assess compliance with national and international standards.

Outcomes of most recent inspections

Agency	Dates of inspection	Date of certification	Outcome
CAP	12/17/10	2/28/11	In compliance with CAP Standards for Laboratory Accreditation
CLIA	12/6/10-12/8/10	4/20/11	In compliance with Part 493 of the Clinical Laboratory Improvement Amendments of 1988 (no deficiencies)
FDA	10/6/09-10/7/09	Certified thru 10/2012	Full accreditation for all procedures
MA DEP	9/8/10	10/19/10	No method deviations observed during on-site visit
CDC SA Program	4/26/11-4/27/11	11/2/11	No major deficiencies

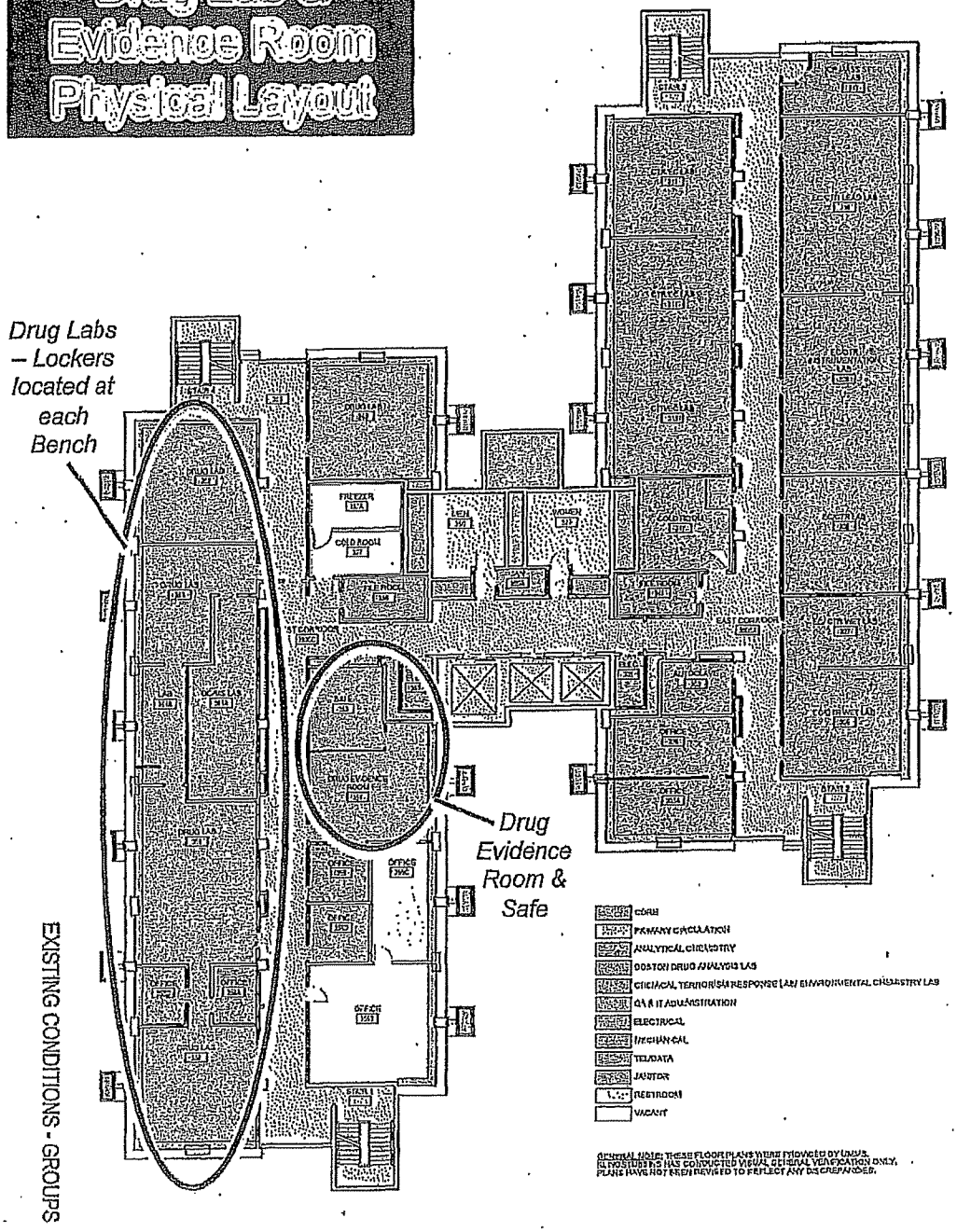
Bureau of Lab Sciences: Laboratory Programs and Associated Federal Oversight 2012

Division	Laboratory	Federal Accreditation/ Certification	Other Federal (or State) Oversight	Last certification/site visit
Analytical Chemistry	Childhood Blood Lead Screening	CLIA, CAP		CAP: 12/2010 inspection, 2/2011 certification CLIA: 12/2010 inspection, 4/2011 certification
	Environmental Chemistry	CLIA	MA Dept Environmental Protection for arsenic and lead in drinking water	CLIA: 12/2010 inspection, 4/2011 certification MA DEP: 9/2010 inspection, 10/2010 certification
	Chemical Terrorism	CLIA	Compliance with LRN and PHEP requirements	CLIA: 12/2010 inspection, 4/2011 certification One of 10 LRN-Chem level 1 laboratories
Molecular Diagnostics and Virology	Virology	CLIA	Compliance with requirements of CDC Select Agent Program	CLIA: 12/2010 inspection, 4/2011 certification CDC SA Prgm: 4/2011 inspection, 11/2011 certification
	Rabies	N/A	Compliance with CLIA standards	Rabies Laboratory Test Challenge: quarterly from the Wisconsin National Proficiency Testing Program (excellent record: all pass)
	Molecular Diagnostics	CLIA		CLIA: 12/2010 inspection, 4/2011 certification
	Arbovirus Surveillance	CLIA	Compliance with requirements of CDC Select Agent Program and CLIA	CLIA: 12/2010 inspection, 4/2011 certification CDC SA Prgm: 4/2011 inspection, 11/2011 certification

	BioWatch	N/A	Compliance with new Department of Homeland Security BioWatch QA/QC program	First Annual Laboratory Inspection due in 2012 Biowatch Annual Proficiency Test Challenge: 2012 (pass with a score of 100%) BioWatch Award of Excellence: 08/2010
Microbiology	Mycobacteriology	CLIA		CLIA: 12/2010 inspection, 4/2011 certification
	Biothreat Response Laboratory	CLIA	Compliance with requirements of LRN, PHEP, and CDC Select Agent Program	CLIA: 12/2010 inspection, 4/2011 certification CDC SA Prgm: 4/2011 inspection, 11/2011 certification
	Enterics	CLIA		CLIA: 12/2010 inspection, 4/2011 certification
	Food	N/A	Working towards ISO accreditation	9/2012: Awarded $1.5M FDA funding to establish ISO accreditation
	Dairy	FDA		FDA: 10/2009 inspection
	Pulse Net	N/A	Compliance with requirements of CLIA, PHEP, and CDC PulseNet Program	Northeast Regional Laboratory All testing personnel are certified by CDC Annual CDC proficiencies passed
	Reference	CLIA		CLIA: 12/2010 inspection, 4/2011 certification
	HIV	CLIA		CLIA: 12/2010 inspection, 4/2011 certification
	STD	CLIA		CLIA: 12/2010 inspection, 4/2011 certification
Central Services	Media and other lab support services	CLIA, CAP, FDA		CAP: 12/2010 inspection, 2/2011 certification CLIA: 12/2010 inspection, 4/2011 certification FDA: 10/2009 inspection

CLIA = Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendment
CAP = College of American Pathologists
LRN = CDC Laboratory Response Network
PHEP= CDC Public Health Emergency Preparedness Cooperative Agreement
ISO = International Standards Organization

Drug Lab & Evidence Room Physical Layout



KLING STUBBINS

TOWER - LEVEL 3 GROUPS
MASSACHUSETTS STATE LAB
Jamaica Plain, MA

DRAFT

Project No: 10-0707-00
DGN File: DPH 0702 ST 1

TWR-03G

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