



Indian Point Energy Center
450 Broadway, GSB
P.O. Box 249
Buchanan, N.Y. 10511-0249
Tel (914) 254-6700

Anthony J. Vitale
Site Vice President

NL-20-052

10 CFR 26.169

July 07, 2020

ATTN: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

Subject: Unsatisfactory 10 CFR 26 Fitness-For-Duty
Blind Performance Testing Results

Indian Point Unit No. 3
Docket No. 50-286
Renewed Facility Operating License No. DPR-64

As required by 10 CFR 26.169, the Health and Human Services (HHS) Certified Laboratory failed to provide Fitness for Duty (FFD) test results within 5 business days of receiving a Blind Performance Specimen.

As required by 10 CFR 26.719(c), this letter is being submitted within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered in performance testing at either a licensee testing facility or an HHS Certified Laboratory, in the testing of quality control or actual specimens. The investigation associated with this issue was completed on June 20, 2020. The attached reports include a description of the issue, investigation results, and associated corrective actions.

Should you have any questions regarding this matter, please contact Mahvash Mirzai, Manager, Regulatory Assurance, Indian Point Energy Center at (914) 254-7714.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony J. Vitale".

AJV/trj

ADZ Z
NSIR

Attachment: 1. Blind Test Specimen Issue
Attachment: 2. Letter from Quest Diagnostics to Dr. Gupta, dated June 15, 2020
Attachment: 3. Letter from Dr. Gupta to Quest Diagnostics, dated June 09, 2020
Attachment: 4. Drug Detail Report
Attachment: 5. Entergy Condition Report CR-IP3-2020-01279
Attachment: 6. Email from Wayne Griffin to Susan Mills
Attachment: 7. Email from Susan Mills to Wayne Griffin

cc: NRC Region I Regional Administrator
NRC Senior Resident Inspector - Indian Point Entergy Center
New York State Dept. of Public Service, Bridget Frymire
NRC Senior Project Manager, Richard Guzman

Blind Test Specimen Issue

Description of Issue

On May 26, 2020, Indian Point Energy Center (IPEC) submitted Blind Performance Specimen #5790842 to the HHS Certified Lab, Quest Diagnostics Norristown PA lab. The Blind specimen substance was certified by the supplier to be positive for Morphine and Codeine. The sample was received at the lab on May 27, 2020, with the results being returned to the Medical Review Officer (MRO) on June 04, 2020, which was outside the 5 business days required for reporting results in accordance with 10CFR26.169 Reporting Results.

Investigation

A request was made to the MRO to have the lab investigate the reason for the specimen reporting outside the 5 business days requirement and on June 09, 2020, the MRO sent a formal request to Quest Diagnostics to investigate the reason for the reporting delay.

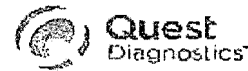
On June 15, 2020, Quest Diagnostics responded that the investigation concluded that the lab received the specimen on May 27, 2020 and on May 30, 2020, confirmatory testing and identification of codeine and morphine was completed. Since the specimen identified morphine as a substance, additional testing, 6-Acetylmorphine (6-AM), was required by the lab. The additional testing did not fully meet the acceptance criteria for the testing; therefore, it had to be repeated. On June 03, 2020, the retest was ordered, and the results were provided on June 04, 2020, which was one day outside the required time for reporting results. In addition, the lab cited that the COVID-19 pandemic had impacted their staffing levels and affected their service levels.

Corrective Actions

Corrective Actions below have been taken and results obtained are;

1. Condition Report (CR-IP3-2020-01279) was generated to document the event,
2. The request from the MRO for Quest Diagnostics to investigate the reason for the delay in reporting has been made
3. The investigation report from Quest Diagnostics outlining their findings have been completed and concluded that the delay in replying was caused by the following factors;
 - I. The results from mass spectrometric confirmatory testing for 6-AM did not fully meet acceptance criteria and a repeat analysis was ordered on June 03, 2020.
 - II. Morphine confirmation testing by gas chromatography-mass spectrometry typically takes several days and any required mass spectrometric confirmatory testing for 6-AM would add an additional 1-2 days to the turnaround time.
 - III. The laboratory staffing levels have been impacted by the pandemic from the COVID-19 virus.
4. Staffing levels are once again increasing at the laboratory which should alleviate this issue

Letter from Quest Diagnostics to Dr. Gupta, dated June 15, 2020



June 15, 2020

Rajesh Gupta, MD
Medical Review Officer
3379 Crompond Road
Yorktown Heights, NY 10598

Re: Specimen ID 5780842

Dear Dr. Gupta:

I am writing to advise you of the causes for the above identified specimen being reported more than 5 business days after receipt at the Norristown, Pennsylvania Quest Diagnostics laboratory. The specimen was received May 27, 2020 and, to be reported within 5 business days, should have been reported by June 3, 2020. It was reported on June 4, 2020.

Reporting for this specimen was delayed for several reasons:

- 1) Confirmatory testing and identification of codeine and morphine was completed on May 30, 2020. The confirmed positive result for morphine prompted an additional test for 6-acetylmorphine (6-AM) which was added on May 30, 2020. The results from the mass spectrometric confirmatory testing for 6-AM did not fully meet acceptance criteria and a repeat analysis was ordered on June 3, 2020.
- 2) Unlike HHS and DOT requirements that 6-AM screening be performed with the initial drug screen, under NRC guidelines, 6-AM testing is not performed until the opiate (morphine) results are completed and there is a confirmed positive result for morphine. Morphine confirmation testing by gas chromatography-mass spectrometry typically takes several days and any required mass spectrometric confirmatory testing for 6-AM would add an additional 1-2 days to the turnaround time.
- 3) The laboratory staffing levels have been impacted by the pandemic from the COVID-19 virus. This does impact service levels.

The process for testing NRC specimens for opiates, the repeat analysis, and staffing levels cited above all contributed to the extended in-lab turnaround time for this specimen. Should you require any more information regarding this, I can be reached at 610-631-4502.

Sincerely,

A handwritten signature in dark ink, appearing to read "Susan Mills".

Susan Mills
Director, Lab Operations

Letter from Dr. Gupta to Quest Diagnostics, dated June 09, 2020



Dr. Rajesh Gupta, Medical Director

3379 Crompond Road (in the BJs Plaza)
Yorktown Heights, New York 10598
(P) 914.930.5550 (F) 914.930-5551

June 9, 2020

To whom it may concern,

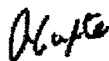
Please accept this letter as formal notice requesting that Quest do an investigation on why the results for Specimen #5790842, which was collected on 5-26-20, received on 5-27-20, and reported out on 6-4-20, as this was not reported in the 5 business days as required by:

"10CFR26.169 (a) The HHS-certified laboratory shall report test results to the licensee's or other entity's MRO within 5 business days after receiving the specimen from the licensee or other entity. Before reporting any test result to the MRO, the laboratory's certifying scientist shall certify the result as correct. The report must identify the substances for which testing was performed; the results of the validity and drug tests; the cutoff levels for each; any indications of tampering, adulteration, or substitution that may be present; the specimen identification number assigned by the licensee or other entity; and the specimen identification number assigned by the laboratory. "

Please advise when you receive this formal request and once the investigation is completed please send report.

Thank you in advance for your attention to this matter.

Sincerely,



Rajesh Gupta, MD, MRO

Drug Detail Report



6/4/2020 8:39:22 AM

Drug Detail Report

PATIENT INFORMATION

Quest Diagnostics Employer Solutions
Customer Care: 800-877-7484

Primary ID: 724417231

SPECIMEN INFORMATION

REQUISITION: 5790842
ACCESSION NO: 8548758
COLLECTED: 5/26/2020 09:12
RECEIVED: 5/27/2020 11:49
REPORTED: 6/4/2020 10:25 ✓
SPECIMEN ID: 5790842 ✓

CLIENT INFORMATION

15112918
ENTERGY INDIAN POINT
450 BROADWAY
BUCHANAN, NY 10511

Reason: PRE-EMPLOYMENT

Blind

COLL SITE PH# 914-254-2193
COLLECTOR'S NAME ANN M PICHETTE
TESTING AUTHORITY NRC

*** POSITIVE/ABNORMAL REPORT ***

Tests Ordered: 1791N, %MORQ2, %CODQ2, %MAMQ2,
24868N, 24868N

Integrity Checks

Acceptable Range

OXIDIZING ADULTERANTS	Negative	
pH	6.9	4.5-8.9
CREATININE	75.7 mg/dL	>= 20 mg/dL

Substance Abuse Panel

		Initial Test Level	GC/MS Confirm Test Level
6-ACETYLMORPHINE	POSITIVE	10 ng/mL	10 ng/mL
AMPHETAMINES	Negative	1000 ng/mL	500 ng/mL
COCAINE METABOLITES	Negative	300 ng/mL	150 ng/mL
MARIJUANA METABOLITES	Negative	50 ng/mL	15 ng/mL
OPIATES		2000 ng/mL	
MORPHINE	(POSITIVE)		2000 ng/mL
CODEINE	(POSITIVE)		2000 ng/mL
PHENCYCLIDINE	Negative	25 ng/mL	25 ng/mL

Quantitative Results

MORPHINE	3401 ng/mL
CODEINE	3314 ng/mL
6-ACETYLMORPHINE	15 ng/mL

CERTIFYING SCIENTIST: WALLNER, DAVID

SPECIMEN RECEIVED AND PROCESSED IN THE

Lab: Quest Diagnostics-Philadelphia
400 Egypt Rd
Norristown PA 19403

<i>Entergy</i>	CONDITION REPORT	CR-IP3-2020-01279
-----------------------	-------------------------	--------------------------

Originator: Griffin, Wayne E	Originator Phone: 2193
Originator Site Group: IP3 Access Authorization IP3	Operability Required: N
Supervisor Name: Colburn, Stephanie M	Reportability Required: N
Discovered Date: 06/09/2020 10:23	Initiated Date: 06/09/2020 12:29

Condition Description:
It was Licensee identified that the results of a Blind Performance Sample were not returned from the HHS Certified Laboratory within the 5 business days as required in 10CFR26.169 and EN-NS-102-03 "Processing Of Fitness Duty Test Results ". The results for Blind Performance Specimen# 5790842 was reported by the HHS Certified lab to the IPEC MRO on the morning of the 6th day.

Immediate Action Description:
MRO office reported the test results of specimen# 5790842 to IPEC as required. Once it was identified that the test results weren't returned within the 5 days, a request to the MRO was made to have the lab investigate the reason for delay in reporting the specimen results.

Suggested Action Description:
CA to investigate the reason for the delay in reporting the specimen results.
CA to provide the investigation report to the NRC within 30 days.

REFERENCE ITEMS:

<u>Type Code</u>	<u>Item Desc</u>
KEYWORDS	5 day
KEYWORDS	Blind Performance
KEYWORDS	Blind sample
KEYWORDS	HHS certified lab

Email from Wayne Griffin to Susan Mills

<rgupta@afcurgentcare.com>; Pichette, Ann M <apichet@entergy.com>
Subject: Specimen 5790842 Investigation Report

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hey Susan,

I received the letter you provided our MRO Dr. Rajesh Gupta on June 15, 2020 explaining the reason for the delay in reporting the drug results for specimen# 5790842 which contained Morphine and Codeine. I readily accept the reasons for the delay as written and appreciate your quick response. I do have one area of possible concern which is listed as reason #3 in your letter. It states that laboratory staffing levels have been impacted by the pandemic of the COVID 19 virus and that it does impact the service levels. This prompts me to ask has the staffing impact been addressed and resolved or could this be a contributor to future delays. Hopefully all is well with your staff and everyone is able to come back to work as normal. We haven't had many of these type of issues or concerns with Quest in the past and you've always provided immediate assistance on the few occasions we have. But since I will am required to report to the NRC the reason for the delay in receiving drug results I need to be able to answer the question of has the lab resolved the staffing issue identified.

Please advise whether actions or measures have been taken to address and resolve the staffing issue.

Wayne E. Griffin

Wayne E. Griffin
IPEC Supervisor, AA/FFD/Medical
450 Broadway
Buchanan, NY 10511
(914) 254-2193 (office)
(845) 490-8486 (cell)

This message is intended for the exclusive use of the intended addressee. If you have received this message in error or are not the intended addressee or his or her authorized agent, please notify me immediately by e-mail, discard any paper copies and delete all electronic files of this message.

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

Email from Susan Mills to Wayne Griffin

Griffin, Wayne E

From: Mills, Susan P <Susan.P.Mills@questdiagnostics.com>
Sent: Monday, June 22, 2020 5:49 PM
To: Griffin, Wayne E
Cc: Slater, Kellie (kslater@afcurgentcare.com); Gupta, Rajesh; Gupta, Rajesh; Pichette, Ann M
Subject: RE: Specimen 5790842 Investigation Report

EXTERNAL SENDER. DO NOT click links, or open attachments, if sender is unknown, or the message seems suspicious in any way. DO NOT provide your user ID or password.

Wayne,

Our section of Pa goes into the green zone the end of this week and we are starting the process to bring staff back to work. You should expect your service levels to be the same as they have been. I believe this specimen was an outlier.

Regards,
Susan

Susan Mills
Director, Laboratory Operations

Quest Diagnostics | Employer Solutions | 400 Egypt Road | Norristown, PA 19403 USA | phone 610.631.4502 | fax 267.436.3526
| Susan.P.Mills@QuestDiagnostics.com | QuestDiagnostics.com

For the latest information on COVID-19 testing, please visit our website:

For healthcare providers: QuestDiagnostics.com/home/Covid-19/HCP/

For patients: QuestDiagnostics.com/home/Covid-19/Patients/

From: Griffin, Wayne E <wgriff1@entergy.com>
Sent: Monday, June 22, 2020 4:01 PM
To: Mills, Susan P <Susan.P.Mills@questdiagnostics.com>
Cc: Slater, Kellie (kslater@afcurgentcare.com) <kslater@afcurgentcare.com>; Gupta, Rajesh <rgupta@afcurgentcare.com>; Gupta, Rajesh