Department of Health and Human Services

**DEPARTMENTAL APPEALS BOARD**

Civil Remedies Division

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| In the Case of: | ) | |
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| Physician Laboratory Technology, Inc., (CLIA Number: 05D0916240) | ) | Date: June 13, 2007 |
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| Petitioner, | ) | |
| | ) | Docket No. C-03-554 |
| - v. - | ) | Decision No. CR1607 |
| | ) | |
| Centers for Medicare & Medicaid Services. | ) | |
| | ) | |

## DECISION

Physician Laboratory Technology, Inc. (Petitioner or laboratory) and Peyman Javaherbin, Petitioner's owner, appealed the Centers for Medicare & Medicaid Services' (CMS) determination to impose a civil money penalty (CMP), cancel Petitioner's approval to receive Medicare payments for its services, and revoke the certificate Petitioner was issued under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), codified at 42 U.S.C. § 263a *et seq.* For the reasons set forth below, I sustain CMS's determination to impose a CMP and revoke Petitioner's CLIA certificate. By operation of law, the owner and operator of Petitioner are prohibited from owning or operating a CLIA laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3) due to the revocation of Petitioner's CLIA certificate.

### I. Background

Petitioner is a clinical laboratory located in Beverly Hills, California. It is owned by Peyman Javaherbin, who established it in 1996. Its director is Iradj Nazarian, M.D. This matter arose as the result of a re-certification survey of Petitioner by the California Department of Health Services, Laboratory Field Services (LFS). The survey completed on November 7, 2002, alleged that the laboratory was out of compliance with seven

conditions of participation under CLIA.[1] In a letter dated November 7, 2002, LFS notified Petitioner of the alleged deficiencies and instructed the laboratory to take the necessary action to bring the laboratory back into compliance. Petitioner submitted several allegations of compliance; however, LFS determined the submissions to be unacceptable. In a letter dated May 1, 2003, CMS informed Petitioner that based on its failure to meet all CLIA conditions and the failure by its owner and the director to comply with certificate requirements and performance standards, CMS was proposing to impose specified sanctions. Petitioner was afforded until May 11, 2003, to submit any evidence or information as to why the proposed sanctions should not be imposed. Petitioner filed a response to CMS's May 1, 2003 letter on May 7, 2003.

On June 16, 2003, CMS informed Petitioner that it found Petitioner's allegation of compliance not to be credible and the evidence provided of alleged corrections not acceptable. CMS further informed Petitioner that it remained out of compliance with the seven Condition-level deficiencies cited as the result of the November 7, 2002 survey. CMS advised Petitioner that it was imposing the following sanctions: (1) revocation of Petitioner's CLIA certificate effective June 30, 2003, if Petitioner did not timely appeal; (2) a CMP in the amount of $3,000 per day to run from May 16, 2003, until compliance was established, or until the laboratory's CLIA certificate was revoked; (3) a directed plan of correction effective June 16, 2003; and (4) cancellation of Petitioner's approval to receive Medicare payments for services performed on or after June 16, 2003. Petitioner was also notified that if revocation of its CLIA certificate was effectuated, the owner and operator (including director) of the laboratory would be prohibited from owning or operating a laboratory for at least two years from the date of revocation pursuant to 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8).

Petitioner timely filed a request for hearing disputing each and every finding of the November 7, 2002 survey. I held a hearing in this case on April 13-14, 2004, in Los Angeles, California. At the hearing, I accepted CMS Exhibits (CMS Exs.) 1-13 into the record. Transcript (Tr.) 11. Petitioner offered Petitioner's Exhibits (P. Exs.) 1-63 into the record. CMS objected to P. Exs. 21-30, 32-34, 36-52, 54-58, and 60, based on relevancy grounds. Tr. 13. Over CMS's objection, I ruled that I would receive into evidence P. Exs. 1-63, but at the end of the hearing, the parties could identify what exhibits should be part of the record. Tr. 20, 386-87. Pursuant to my Transmittal of Transcript Order of May 5, 2004, the parties were directed to file a joint submission indicating which exhibits were to be part of the record in this case. The parties did not file a joint submission. CMS submitted a letter dated June 14, 2004, in which it stated that "Petitioner and CMS agree that the following exhibits originally submitted by Petitioner should <u>not</u> be a part of

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[1] All citations are to the 2002 version of the Code of Federal Regulations, which was in effect at the time of the November 2002 survey. The CLIA regulations were amended in January 2003.

the record in this case, and should be excluded: Petitioner's exhibits 34, 36-43, 45-53, 56, 58, and 59. However, the parties disagree with respect to the inclusion of certain exhibits, and therefore CMS is filing its response to the May 5, 2004 Order separately from Petitioner." In its letter, CMS argued that Petitioner's exhibits 21-30, 32, 44, 45, 54, 55, 57, and 60 should also be excluded because they were irrelevant.[2] Petitioner submitted a Final Exhibit List on June 11, 2004. Petitioner stated that it "submits this . . . List separately because [Petitioner] and CMS are in disagreement as to whether certain exhibits should be included. [Petitioner] and CMS agree that the following [Petitioner] exhibits should be admitted: 1-20, 31, 33, 35, and 61-63. [Petitioner] and CMS agree that the following exhibits were not discussed at the hearing and should be excluded: 34, 36-43, 45-53, 56, 58, and 59." Petitioner argues that the following exhibits in dispute should also be admitted: 21-30, 44, 54, 55, 57, and 60.[3]

Because the parties were unable to agree on which of Petitioner's exhibits should be part of the record, I have decided that all of Petitioner's exhibits shall remain in the record. I have accorded them the weight I determined they warrant.

Surveyor Elsa Eleco, Examiner for the LFS, and Gary Yamamoto, Laboratory Consultant with CMS, testified on behalf of CMS. Petitioner's owner, Peyman Javaherbin, testified on behalf of Petitioner. CMS submitted a posthearing brief (CMS Br.), and Petitioner submitted a posthearing response brief (P. Br.). CMS subsequently submitted a posthearing reply brief (CMS R. Br.). A transcript of the hearing was prepared and distributed to both parties.

My decision in this case is based upon my review and consideration of the record exhibits, the testimony of the witnesses presented at hearing, and the arguments advanced by both parties.

## II. Applicable law

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, *codified at* 42 U.S.C. § 263a *et seq*. The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and hence, the public health of all Americans. *See* H.R. Rep. No. 100-899, at 8, 18

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[2] I note that CMS mistakenly listed P. Ex. 45 as being in dispute. The parties had agreed that P. Ex. 45 was among the exhibits to be excluded.

[3] I note that Petitioner overlooked mentioning P. Ex. 32 as being among the disputed exhibits.

(1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. CLIA grants the Secretary of Health and Human Services (the Secretary) broad enforcement authority, including the ability to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more requirements for certification. The Secretary has exercised his authority under 42 U.S.C. § 263a(f) and issued regulations implementing CLIA. *See* 42 C.F.R. Part 493.

The Secretary's regulations delegate to CMS broad authority to ensure that laboratories perform as Congress intended, including authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. CMS certification of a laboratory under CLIA is dependent upon whether the laboratory meets the conditions for certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1); 42 C.F.R. § 493.1 *et seq.* Pursuant to the enforcement provisions of the regulations, CMS may impose principal or alternative sanctions when it finds that a laboratory has a "condition-level" deficiency. 42 C.F.R. § 493.1804(b)(2). Principal sanctions are suspension, limitation, or revocation of a CLIA certificate. 42 C.F.R. § 493.1806(b). Alternative sanctions are a directed plan of correction, state on-site monitoring, and a CMP. 42 C.F.R. § 493.1806(c). Cancellation of Medicare payments is also authorized as a principal sanction when condition-level deficiencies are found (42 C.F.R. §§ 493.1807(a) and 493.1842(a)(2)) and required when CMS suspends or revokes a laboratory's certificate (42 C.F.R. § 493.1842(a)). Standard-level deficiencies are not an adequate basis for the imposition of a sanction, except when the laboratory fails to correct such deficiencies within 12 months after the last day of inspection. 42 C.F.R. § 493.1816(b).

The regulations establish both *conditions* and *standards* of participation under CLIA. Each condition-level requirement of the regulations represents a major division of laboratory services to be offered by the laboratory or establishes an important environmental protection for the laboratory. Standards of participation are set forth as specific quality requirements which must be met by a laboratory in order to meet the more general requirements of conditions of participation. Thus, standards are subparts of the more broadly stated conditions. A failure by a laboratory to comply with one or more standards may be so serious as to constitute a failure to comply with the condition of which the standards are subparts. *Vijay Sakhuja, M.D.*, DAB No. 1958 (2005).

Further, failure by a laboratory to comply with even a single applicable condition can represent a critical breakdown in one of the major health care delivery or safety systems of the laboratory. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). Therefore, violation of just one condition-level deficiency can be grounds for a principal sanction, including revocation of a laboratory's CLIA certificate. 42 C.F.R. § 493.1804(b); *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999).

In addition to sanctions directed against laboratories, CLIA provides the following with respect to the owners and operators of non-compliant laboratories:

> No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section.

42 U.S.C. § 263a(i)(3).

The implementing regulations do not include any express provision implementing or imposing this two-year prohibition against an offending owner or operator. However, the regulations provide that CMS may suspend, limit, or revoke a laboratory's CLIA certificate if it finds that the owner or operator has –

> [w]ithin the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

42 C.F.R. § 493.1840(a)(8).

CLIA does not include a definition of the term operator. However, the regulations define an "operator" as:

> the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes –
>
> > (1) A director of the laboratory if he or she meets the stated criteria . . . .

42 C.F.R. § 493.2.

The "stated criteria" for a laboratory director to be considered an operator are those criteria described in the introductory sentence of the above-quoted section, *i.e.*, whether a person oversaw all facets of the operation of the laboratory and bore primary responsibility for the safety and reliability of the results of specimen testing performed in

the laboratory. *Sentinel Medical Laboratories, Inc.*, DAB No. 1762, at 13 (2001), *aff'd, Teitelbaum v. Health Care Financing Admin.*, No. 01-70236 (9th Cir. Mar. 15, 2002), *reh'g denied*, No. 01-70236 (9th Cir. May 22, 2002); *Sol Teitelbaum, M.D.*, DAB No. 1849, at 8 n.7 (2002). It is a condition-level requirement that a CLIA-certified laboratory have a qualified laboratory director who is required to assume oversight and responsibility for the laboratory and the results of its testing. *See* 42 C.F.R. §§ 493.1403, 493.1405, 493.1407, 493.1441, 493.1443, and 493.1445. Thus, the regulation creates a rebuttable presumption that a laboratory director is an operator of the laboratory within the meaning of the regulations and CLIA.

The burden of proof in an appeal of CMS's sanctions is governed by the decision in *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Center v. U.S. Dep't. of Health and Human Services*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999); *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999) (*Hillman* burden of proof applicable in CLIA appeals). CMS has the burden of providing evidence that is sufficient to establish a *prima facie* case. Petitioner then has the burden of coming forward with evidence sufficient to establish by a preponderance of the evidence the elements of its defense or affirmative arguments.

## III. Issues

Whether one or more condition-level deficiencies existed at Petitioner.

Whether there is a basis for the revocation of Petitioner's CLIA certificate and the imposition of other remedies.

## IV. Findings of fact, and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each of my Findings below as a separate heading. I discuss each Finding in detail.

The Statement of Deficiencies (SOD) in this case consists of 76 pages. CMS Ex. 1; P. Ex. 1. CMS alleges that Petitioner was out of compliance with seven CLIA conditions, as well as numerous other standard-level requirements imposed by the CLIA regulations. The conditions which CMS alleges were not met are: (1) General Quality Control (42 C.F.R. § 493.1201); (2) Endocrinology (42 C.F.R. § 493.1247); (3) Laboratory Director, high complexity testing (42 C.F.R. § 493.1441); (4) Technical Supervisor, high complexity testing (42 C.F.R. § 493.1447); (5) General Supervisor, high complexity testing (42 C.F.R. § 493.1459); (6) Testing Personnel, high complexity testing (42 C.F.R. § 493.1487); and (7) Quality Assurance (42 C.F.R. § 493.1701).

### A. CMS established a prima facie showing that Petitioner was out of compliance with one or more conditions, and Petitioner did not rebut that showing by the preponderance of the evidence.

I do not discuss in this decision every alleged deficiency, or subsection of deficiency, cited by CMS. The Departmental Appeals Board (DAB or Board) has previously upheld an administrative law judge's (ALJ) decision to exercise judicial economy and not discuss every alleged deficiency. *Beechwood Sanitarium*, DAB No. 1824, at 22 (2002). As previously noted, the Board has held that the failure by a laboratory to comply with even a single applicable condition may be grounds for the revocation of the laboratory's CLIA certificate. *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999); *Vijay Sakhuja, M.D.*, DAB No. 1958 (2005).

Indeed, in many instances, Petitioner admits to the deficiencies, often offering little or no legally defensible position. Petitioner's arguments often fail to address the facts of the cited deficiencies or discuss them in terms of the text of the regulations.[4] As I explain below, I find there is a sufficient basis to affirm CMS's revocation of Petitioner's CLIA certificate as well as the other remedies CMS has chosen to impose in this case.

#### 1. Petitioner was out of compliance with the condition of General Quality Control as set forth in 42 C.F.R. § 493.1201.

The condition for General Quality Control requires that a laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. CMS alleges, among other things, that Petitioner failed to: (1) verify and establish the analytical sensitivity of the Abbott AxSYM Follicle-Stimulating Hormone (FSH)[5] and Abbott AxSYM Luteinizing Hormone tests prior to reporting patient test results;[6] (2) verify and establish its reportable range for the Coat-A-Count Free Testosterone test prior to reporting patient test results; (3) perform calibration procedures in accordance with manufacturer's instructions; (4) document all calibration and calibration verification procedures performed; and (5) issue corrected reports and maintain these corrected reports with exact duplicates of the original reports for two years. CMS Ex. 1, at 14-15. I do not discuss each one of these alleged deficiencies.

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[4] In its posthearing reply brief, CMS describes Petitioner as making a "half-hearted, after-the-fact attempt to minimize its admitted failures." CMS R. Br. at 11.

[5] This test is commonly used to evaluate a women's egg supply or a man's low sperm count. *See Merck Manual*, 68 (17th ed. 1999).

[6] I only discuss Petitioner's FSH testing in this decision.

**FSH Testing**

**a. Prior to reporting patient test results, Petitioner failed to verify or establish the analytical sensitivity of the Abbott AxSYM FSH test, in violation of 42 C.F.R. § 493.1213(b)(2)(i).**[7]

To perform FSH testing, Petitioner used the Abbott AxSYM FSH test. According to the manufacturer's package insert, the established analytical level of sensitivity for the test was 0.37 mIU/mL. CMS Ex. 8, at 16. The insert noted further that sensitivity "represents the lowest measurable concentration of FSH that can be distinguished from zero." *Id.*

Petitioner admits that the results that it reported for FSH were lower than the manufacturer's established sensitivity level of 0.37 mIU/mL. At the hearing, Mr. Javaherbin admitted that they were "reporting out a result of 0.1 or 0.2 versus ['']less than 0.37.['']" Tr. 332 (inner quotes added).[8] There is no dispute that, during the period November 1, 2001 through May 22, 2002, Petitioner reported 49 patient FSH test results with values below the established sensitivity level of 0.37 mIU/mL. CMS Ex. 6.[9]

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[7] The regulation at 42 C.F.R. § 493.1213(b)(2)(i) states that "[e]ach laboratory that introduces a new method or device as specified in either § 493.1202(a) or (b), or § 493.1203(a), must, prior to reporting patient test results – (i) Verify **or** establish for each method the performance specifications for the following performance characteristics, as applicable . . ." (Emphasis added).

In the SOD, when discussing the alleged deficiencies relative to this regulation, CMS often alleges that Petitioner failed to "verify **and** establish" one of the enumerated performance characteristics, rather than stating "verify or establish," as the text of the regulation states. *See e.g.,* CMS Ex. 1, at 14, 15, 17, and 21. I note that this is a distinction without a difference, inasmuch as Petitioner neither verified nor established the analytical sensitivity or the reportable range of the Abbott FSH and Coat-A-Count Free Testosterone tests.

[8] I have added the inner quotes to Mr. Javaherbin's testimony for the sake of clarification. This aspect of Mr. Javaherbin's testimony was not emphasized in the transcript. *See* P. Br. at 9-11.

[9] CMS Ex. 6 consists of Petitioner's laboratory reports of patient test results from the period November 1, 2001 through May 22, 2002. The FSH test is listed under "Hormonal Studies," and these reports show that Petitioner reported FSH tests results of "0.0," "0.1," "0.2," or "0.3" mIU/mL, CMS Ex. 6; *see* CMS Prehearing Br. at 11-12.

He testified that the reason the machine reported specific values under 0.37, rather than reporting "less than 0.37," is because the manufacturer, Abbott, set up the machine to report out values under 0.37 mIU/mL. Tr. 329, 334. Petitioner points to a letter from the manufacturer, Abbott, dated October 23, 2003, in which Abbott states that it "is responsible for all studies and validations for the AxSYM instrument upon installation . . . At [Petitioner], method validations studies that were performed and [sic] included the following: precision, minimum detection, reportable range, and patient correlation." P. Ex. 21. Mr. Javaherbin admitted that nothing in this memo states that the manufacturer, Abbott, had validated results lower than 0.37 mIU/mL for FSH tests. Tr. 368.

On cross-examination, Mr. Javaherbin claimed that it was Petitioner's policy to perform tests according to the manufacturer's inserts. Tr. 369. He stated that a laboratory has "leeway," and can either follow the manufacturer's inserts or do its own validation studies and come up with its own numbers. Tr. 370. Mr. Javaherbin admitted that, if a laboratory has not conducted its own validation studies and has not validated the sensitivity below the established analytical sensitivity, then it would be standard practice to follow the manufacturer's insert. Tr. 370.

Petitioner submitted no evidence to establish that the manufacturer had validated FSH results below 0.37 mIU/mL. Moreover, Petitioner failed to produce any evidence that it had conducted its own validation studies and thereby verified and established a sensitivity level below the manufacturer's established sensitivity level of 0.37 mIU/mL, prior to reporting patient test results.

In Petitioner's view, "[t]his is making a mountain out of a molehill." P. Br. at 10. Petitioner contends that because 0.37 mIU/mL "represents the lowest measurable concentration of FSH that can be distinguished from zero," any reported test result that is below 0.37 mIU/mL is essentially the same as zero and has no clinical significance. According to Mr. Javaherbin, reporting "0.37 versus 0.1 or 0.0 has no bearing on the patient" and makes no clinical difference. Tr. 332. Petitioner argues that no patients were harmed because it reported test result values lower than 0.37 mIU/mL "rather than simply stating 'lower than 0.37 mIU/mL.'" P. Br. at 10.

Petitioner's arguments reflect a common theme throughout its brief and demonstrate its apparent inability to grasp the critical point. The purpose of CLIA and the implementing regulations is to ensure public health and safety by ensuring that laboratories provide accurate and reliable test results. Under CLIA regulations, the test is not merely whether small errors were made or whether patients were harmed; but rather it is whether the laboratory established and followed general quality procedures for monitoring and evaluating the quality of the analytical testing process of each testing method to assure the accuracy and reliability of patient test results and reports.

By failing to verify or establish the analytical sensitivity of the FSH test before reporting patient test results, Petitioner violated the standard established by 42 C.F.R. § 493.1213(b)(2)(i).

**Free Testosterone Testing**

**b. Prior to reporting patient test results, Petitioner failed to verify or establish its reportable range for the Coat-A-Count Free Testosterone assay, in violation of 42 C.F.R. § 493.1213(b)(2)(i). Petitioner also failed to substantiate the continued accuracy of the test method throughout the laboratory's reportable range for patient results, in violation of 42 C.F.R. § 493.1217.**

For free testosterone testing, Petitioner used the Diagnostic Product Corporation's (DPC) Coat-A-Count Free Testosterone assay, a procedure designed for the "quantitative measurement of free testosterone in serum." CMS Ex. 8, at 2. Among other things, the manufacturer's package insert for the test kit gives instructions for the test, describes how specimens should be collected and handled, and explains how results should be calculated. CMS Ex. 8, at 1-7.

The SOD alleged that, prior to reporting patient test results, Petitioner failed to verify and establish its reportable range for the Coat-A-Count free testosterone testing. CMS Ex. 1, at 14-15, 21-23. The SOD alleged further that Petitioner had no documentation to show that it established and verified the accuracy of patient results beyond the upper limit of the manufacturer's reportable range (50 pg/mL). CMS Ex. 1, at 23.

According to CMS, the manufacturer's insert stated that the calibrator values are "lot-specific" and the highest calibrator value is 50 pg/mL. CMS Ex. 1, at 21; *see* CMS Ex. 8, at 2. CMS alleged that, for 75 patient test results from the period February 14, 2002 through May 22, 2002, Petitioner reported free testosterone results which were higher than the assay's upper calibration limit of 50 pg/mL. CMS Ex. 1, at 21-23. The test's normal range, i.e. the reference range used by Petitioner, for adult males 20 to 49 years of age was either 12 - 40 pg/mL or 12.4 - 40 pg/mL. CMS Ex. 10, at 4; *see e.g.*, CMS Ex. 6, at 7, 11, 14, 29, 71, 79.

At the hearing, LFS Surveyor Elsa Eleco testified that one would have to look at the calibrator vials to obtain the calibrator values, which would determine the upper limit for that particular assay lot. Tr. 44; *see* CMS Ex. 8, at 3. According to Ms. Eleco, the upper limit value would be the "upper limit of your reportable results" unless the laboratory validated a calibration that was higher than the lot-specific calibration. Tr. 44-45.

Surveyor Eleco testified on cross-examination that Petitioner used incorrect calibrator values, which resulted in its reporting free testosterone test results that were incorrect and on the high side. Tr. 212. Ms. Eleco stated that, according to the manufacturer, the highest calibrator value for the Coat-A-Count free testosterone assay Petitioner was using was "approximately 50 [pg/mL]. Tr. 44. She stated that this meant that the upper limit for reporting results would be 50 pg/mL, and for any test result higher than 50 pg/mL, a validation study was required to ensure that the result was accurate and reliable. Tr. 44-46; 139. Ms. Eleco testified further that, if a laboratory has not validated above what the manufacturer set the upper limit at, then it should not report results based on that number. Tr. 45. When asked whether there is a standard practice for reporting results above the established upper limits, she stated that, if the upper calibration limit is 50 pg/mL, then one would usually report the result "as [']greater than 50 [pg/mL].[']" Tr. 45 (inner quotes added).[10]

Ms. Eleco testified that Petitioner did record patient results above 50 pg/mL. Tr. 46; *see* Tr. 50-51. For example, she stated that a test report for accession No. 48268 (CMS Ex. 6, page 7) showed a free testosterone result of 1,120 pg/mL that was reported by Petitioner. Tr. 50-51. Ms. Eleco stated that this value is "way above" the manufacturer's established calibration range for this test. Tr. 51.

Ms. Eleco testified further that at the time of the survey, she found no evidence that Petitioner had conducted validation studies for results above 50 pg/mL. Tr. 46. Ms. Eleco stated that reporting values above the manufacturer's established highest calibration value is problematic because

> [y]ou could not determine the accuracy or the reliability of the results cause the test system is designed and validated and approved to have a calibration limit or reportable range of 50 [pg/mL]. Anything over that you can't verify the accuracy and the reliability . . . .

Tr. 51. I find that Petitioner failed to provide any documentation that it conducted its own validation studies to ensure the accuracy and reliability of the results above 50 pg/mL.

Petitioner does not dispute that it reported free testosterone results well above the manufacturer's upper calibration limit. At the hearing, Mr. Javaherbin admitted that, for the period at issue, the free testosterone results were "off." Tr. 341-42. Petitioner's counsel summarized Mr. Javaherbin's testimony at one point, stating "[t]he witness has

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[10] I have added the inner quotes to Ms. Eleco's testimony for the sake of clarification. This critical aspect of her testimony – that if a free testosterone test result was higher than 50 pg/mL, then Petitioner should have reported the result as "greater than 50 pg/mL" – was not emphasized in the transcript. *See* P. Br. at 9.

testified, Your Honor, that for the DPC [Diagnostic Products Corporation – the manufacturer of the Coat-A-Count free testosterone test] over that three month period because they used the wrong data reduction and the values, the numbers were out of compliance on the higher side, okay ?" Tr. 349.

Because Petitioner reported free testosterone results outside of the calibration range of the test, and had not conducted any studies that validated results above the manufacturer's upper limit of 50 pg/mL, I conclude that Petitioner also failed to substantiate the continued accuracy of the test method throughout its reportable range for patient test results.

Petitioner attempts to minimize the significance of the high free testosterone results, asserting that Ms. Eleco herself testified that high testosterone levels merely indicate that a patient is either hairy or very bald. P. Br. at 7. Petitioner maintains that because the results of the tests were seemingly innocuous, with no adverse impact on patient care, and no physician receiving the results complained, then no deficiency exists. P. Br. at 4, 7. However, as CMS points outs, the fact that no one was harmed or no one complained does not establish compliance with the regulations. *See* CMS Br. at 11. Physicians rely upon laboratory results to make treatment decisions, and CLIA requires that laboratory testing be done in a manner that is accurate and reliable.

Petitioner has admitted that it was not in compliance with the requirements of 42 C.F.R. § 493.1213(b)(2)(i). Petitioner's admission, coupled with the evidence advanced by CMS, leads me to conclude that CMS has made a prima facie showing as to this deficiency. The evidence also establishes that CMS has made a prima facie showing that Petitioner failed to comply with the requirements of 42 C.F.R. § 493.1217. I find that Petitioner has not rebutted the prima facie evidence for either standard-level violation by a preponderance of the evidence.

I conclude that the violations of 42 C.F.R. § 493.1213(b)(2)(i) and 42 C.F.R. § 493.1217 amount to a condition-level violation of 42 C.F.R § 493.1201, the Condition of General Quality Control.

**2. Petitioner was out of compliance with the Condition pertaining to Endocrinology at 42 C.F.R. § 493.1247.**

The Condition pertaining to Endocrinology at 42 C.F.R. § 493.1247 states that, to meet the quality control requirements for endocrinology, a laboratory performing moderate or high complexity testing must comply with the applicable requirements contained in 42 C.F.R. §§ 493.1201 (General Quality Control Condition) through 493.1221, and must document all quality control activities. The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical

testing process of each method to assure the accuracy and reliability of patient test results and reports.

In setting forth the alleged deficiencies under this condition, the SOD referenced citations that were previously alleged in connection with Petitioner's violation of the General Quality Control Condition at 42 C.F.R. § 493.1201. CMS Ex. 1, at 49-50; *see* CMS Ex. 1, at 14-15. Under the condition for Endocrinology, the SOD alleged the following deficiencies: (1) failure to verify and establish the analytical sensitivity for the Abbott FSH and Luteinizing Hormone tests, prior to reporting patient test results (42 C.F.R. § 493.1213(b)(2)(i)); (2) failure to verify and establish its reportable range for the Coat-A-Count free testosterone testing, prior to reporting patient test results (42 C.F.R. § 493.1213(b)(2)(i)); (3) failure to ensure the accuracy of the test method throughout the laboratory's reportable range for patient results (42 C.F.R § 493.1217)); (4) failure to perform calibration procedures in accordance with manufacturer's instructions (42 C.F.R. § 493.1217(b)(1)(i)); and (5) failure to issue corrected reports and maintain these corrected reports with exact duplicates of the original reports for two years (42 C.F.R. § 493.1219(d)). CMS Ex. 1, at 49-50.

At the hearing, Surveyor Eleco testified that the Luteinizing Hormone, FSH, and free testosterone tests are endocrinology tests, and that endocrinology is a subspecialty under chemistry. Tr. 100. In my discussion of the General Quality Control condition (42 C.F.R. § 493.1201), I discussed only Petitioner's FSH and free testosterone testing. My conclusion that Petitioner was in violation of the General Quality Control condition was based on my findings that Petitioner had violated quality control standards for these two test processes. Specifically, I concluded that Petitioner failed to verify or establish the analytical sensitivity for the Abbott FSH test, prior to reporting patient test results. I also concluded that, prior to reporting patient test results, Petitioner failed to verify or establish its reportable range for the Coat-A-Count Free Testosterone testing. Furthermore, because Petitioner reported patient test results beyond the test's calibration range, I found that Petitioner also failed to substantiate the continued accuracy of the test method throughout its reportable range for patient test results.

With respect to the allegation regarding calibration, the SOD alleges that Petitioner failed to perform calibration procedures on the Abbott QwikWash Bead Washing System, as specified by the manufacturer. *See* CMS Ex. 1, at 25. The SOD states that this instrument was used when Petitioner performed hepatitis and HIV antibody immunoassays on the Abbott Quantum II analyzer. *See* CMS Ex. 1, at 25, 41. CMS submitted from the manufacturer's QwikWash manual a page of instructions titled "Calibration Procedure: Volume Verification" taken. CMS Ex. 8, at 13-14. These instructions state that the calibration procedure described "verifies that the amount of water used in the wash cycle is within QwikWash specifications." The instructions state

further that the procedure should be performed daily. CMS Ex. 8, at 14.

Surveyor Eleco testified that, during the survey, she saw no records to verify that Petitioner had "tested the washing of the beads" to ensure that it was washing the beads "with the prescribed amount [of water] between 11 to 17 milliliters." Tr. 231. She stated that "any underfill or overfill would affect your test result" and that the right amount of water needed to be used. Tr. 56, 231-32; *see* Tr. 57. Surveyor Eleco testified that Petitioner did not produce any documentation that Petitioner was performing the calibration procedure for the Abbott QwikWash Bead Washing System. Tr. 56-57, 232. She stated that Petitioner couldn't find any records after September 2000. Tr. 233.

Mr. Javaherbin explained that antigen-coated beads are washed in this instrument. He stated that the beads are used in testing in conjunction with the hepatitis markers (hepatitis A, hepatitis B, hepatitis C and HIV). Tr. 353-54.

According to Mr. Javaherbin's testimony, he did have records but didn't give them to Surveyor Eleco because he could not find them. Mr. Javaherbin stated the records were kept in a "thin binder," and "must have been thrown out by mistake." Tr. 352. He stated that he looked all over the laboratory for it, and that they kept records on a daily basis as to "how much water is being delivered into the wash blade." *Id.*

Mr. Javaherbin stated that they "have records going back from opening of the lab 1996 to 2000." He admitted, however, that "[j]ust the current records was [sic] somehow thrown out." Tr. 352. Mr. Javaherbin also gave a more specific admission, stating "[s]o in getting the right amount [of water] delivered we were recording it, just for some reason, somehow that record was thrown out." Tr. 353.

Mr. Javaherbin himself acknowledged the importance of making sure the correct amount of water is used in the washing process. He testified:

> If we do not wash it and we do not get correct amount of water delivered into that system, our controls will not come out for one thing, and you know, we would get wrong results. I mean, that's definitely - - if that amount of water is not right, you get the wrong result and that will show on your controls.

Tr. 353.

Mr. Javaherbin contended that he checked their controls, and "they were all in." *Id.*

In its posthearing brief, Petitioner argues that it received 100% in proficiency testing for hepatitis and HIV for the period in question, and that this demonstrates that the beads

must have been washed as required. P. Br. at 12-13. Petitioner contends also that the 100% score shows that "there was no adverse effect on patient testing." Tr. 13.

Based on Petitioner's admissions and its failure to produce any documentation, I find that Petitioner failed to prove that it was performing the calibration procedures for the Abbott QwikWash Bead Washing System in accordance with the manufacturer's instructions. Petitioner submitted no evidence that demonstrated it actually verified that the correct amount of water was being used as noted in the manufacturer's insert. Nor did Petitioner produce any laboratory personnel who testified that calibration procedures were actually conducted. Moreover, Petitioner's attempt to use its proficiency testing scores to rebut CMS's case misses the point. Petitioner's proficiency testing scores have no relation whatsoever with the calibration requirements and do not in any way prove that Petitioner performed calibration procedures as required under the regulations on the Abbott QwikWash Bead Washing System.

As another example of Petitioner's failure in the area of calibration verification, the SOD also alleged that, from February 14, 2002 through May 21, 2002, Petitioner failed to use the manufacturer-assigned calibrator values for the free testosterone tests. CMS Ex. 1, at 25. The SOD states that Petitioner routinely used DPC's Coat-A-Count free testosterone test kits, and that the manufacturer's package insert indicated in the procedures section: "The values of the calibrators are lot-specific. Refer to the calibrator vial labels for values in pg/mL." CMS Ex. 1, at 26; CMS Ex. 8, at 3. The SOD alleges that Petitioner failed to program the correct calibrator values into the assay protocol for the period February 14, 2002 through May 21, 2002. CMS Ex. 1, at 26.

Mr. Javaherbin admitted several times that, during the period February 14 to May 21, 2002, Petitioner did not use the correct calibrator values for the Coat-A-Count free testosterone assay. Tr. 341, 358, 373, 377. He testified that around February 2002, a new technologist (Ms. Nakar) started, and that she "did not correct the data reduction and also did not program the new calibrated values. As of that time we started having problems." Tr. 341; see Tr. 372.

Mr. Javaherbin further admitted that, from February 14, 2002 until the survey, no one in the laboratory identified that incorrect calibrator values were being used. Tr. 377. Petitioner did not dispute that it reported free testosterone test results based on incorrect calibrator values during the period February 14, 2002 through May 21, 2002.

I conclude that, with respect to the QuikWash instrument and free testosterone testing, CMS made a prima facie showing that Petitioner failed to perform calibration procedures in accordance with manufacturer's instructions using calibration materials provided or specified. Petitioner failed to rebut CMS's prima facie showing by a preponderance of

the evidence.

I find that the foregoing standard-level violations constitute a condition-level violation of the Condition for Endocrinology at 42 C.F.R. § 493.1247.

**3. Petitioner was out of compliance with the Condition of Laboratory Director for laboratories performing high complexity testing, in violation of 42 C.F.R. § 493.1441.**

The SOD alleges that Petitioner's laboratory director failed to meet the requirements of the Laboratory Director Condition at 42 C.F.R. § 493.1441 based on his failure to provide overall management and direction in accordance with 42 C.F.R. § 493.1445. Specifically, the SOD alleged the following standard-level deficiencies: (1) failure to ensure that laboratory personnel were performing tests as required for accurate and reliable results (42 C.F.R. § 493.1445(e)(3)(iii)); (2) failure to ensure that quality control programs were established to assure the quality of laboratory services provided (42 C.F.R. § 493.1445(e)(5)); (3) failure to ensure that quality assurance programs were established and maintained to assure the quality of laboratory services provided (42 C.F.R. § 493.1445(e)(5)); and (4) failure to employ laboratory personnel with the required qualifications, under State law (42 C.F.R. § 493.1445(e)(11)). CMS Ex. 1, at 55.

CMS contends that Petitioner failed to perform Coat-A-Count free testosterone tests as required for accurate and reliable results. CMS asserts that the manufacturer's package insert for the free testosterone test explicitly prohibits dilution: "Do not attempt to dilute patient samples expected to contain high concentrations in the zero calibrator." CMS Br. at 31 (quoting CMS Ex. 8, at 3). CMS points out further that the insert stated "[s]ince dilution shifts the equilibrium between free and bound testosterone, the assay system cannot be expected to maintain linearity under dilution." CMS Br. at 31 (quoting CMS Ex. 8, at 3). Ms. Eleco testified that dilution "skews the results." Tr. 104; *see* Tr. 137.

CMS contends that, despite the insert's instructions, Petitioner's testing personnel diluted at least three patient samples during the relevant time period and reported Coat-A-Count free testosterone test results for those samples based on dilution.[11] CMS Ex. 1, at 56; *see* CMS Ex. 6, at 7, 31, and 34; CMS Ex. 7, at 6, 15; Tr. 103–04.

I find that Petitioner offered no meaningful rebuttal to overcome CMS's prima facie showing. By failing to ensure that laboratory personnel followed the instructions

[11] The SOD alleges that Petitioner's testing personnel diluted four patient samples; however, in its brief, CMS specifically mentions only three patient test results that were reported based on dilution. CMS Br. at 31.

prohibiting dilution of patient samples, Petitioner's laboratory director failed to ensure that testing personnel conducted tests as required for accurate and reliable results.

With respect to the laboratory director's failure to ensure that quality control programs were established, I note that the SOD cross-references the tags pertaining to the General Quality Control and Endocrinology condition-level deficiencies. CMS alleges in its brief that no quality control programs were "being utilized on any regular basis." CMS Br. at 33. As support for this, CMS asserts that Petitioner "went three months using incorrect calibrator values, incorrect data reduction methods, reporting beyond the reportable range, and had no documented proof of calibration verification." CMS Br. at 33. Although I have not discussed Petitioner's data reduction methods, I have concluded above that Petitioner had conducted inaccurate free testosterone testing using incorrect calibrator values, reported results above the manufacturer's established upper calibration limit, and provided no evidence that it had conducted validation studies for results above the upper limit. Given Petitioner's failures in these areas, I find that Petitioner's laboratory director failed to ensure that quality control programs were established to assure the quality of laboratory services provided.

Petitioner was also cited for its laboratory director's failure to ensure that quality assurance programs were established and maintained. I find that Petitioner has not rebutted this alleged deficiency by a preponderance of the evidence. Because CMS also alleged a condition-level violation of Quality Assurance (42 C.F.R. § 493.1701), I will discuss Petitioner's deficiencies in quality assurance in greater detail as part of my discussion of the condition-level violation.

Another example of Petitioner's failure to comply with the requirements of the Laboratory Director Condition is demonstrated by the fact that the laboratory director failed to employ laboratory personnel with the required qualifications, pursuant to 42 C.F.R. § 493.1445(e)(11). As stated above, Petitioner used the Coat-A-Count Free Testosterone test kit by radioimmunoassay testing to conduct free testosterone testing. This free testosterone test is a high complexity test classified under the specialty of chemistry, in the subspecialty of endocrinology. CMS Ex. 1, at 60; Tr. 101. Surveyor Eleco testified that, at the time of the survey, she was informed that Mr. Peyman Javaherbin was the technical supervisor for the Coat-A-Count Free Testosterone testing. Tr. 239; *see* Tr. 110, 114. She testified also that Mr. Javaherbin was Petitioner's general supervisor at the time of the survey. Tr. 134, 135. She stated that Mr. Javaherbin possessed a "limited license," in microbiology (Tr. 111), which meant that he could only have acted as a supervisor in the specialty of microbiology or its subspecialties. Tr. 134. Surveyor Eleco testified that, because his license was limited to microbiology, Mr. Javaherbin was not authorized to supervise high complexity testing in chemistry under California state law. Tr. 114, 133-34. On cross-examination, Mr. Javaherbin admitted

that his license does not qualify him to supervise in chemistry, hematology, and endocrinology. Tr. 358.

CMS also maintains that documentary evidence indicates that Mr. Javaherbin was also testing in other areas beyond the scope of his limited license. The record contains a laboratory personnel form dated May 30, 2002 (P. Ex. 14, at 164) that indicates that Mr. Javaherbin was performing testing in microbiology, immunology, chemistry, and hematology. Mr. Javaherbin admitted that his license does not cover chemistry or hematology. Tr. 355.

Petitioner argues that CMS was mistaken, and, in fact, Zenaida ("Nidi") Nakar was the technical supervisor for the free testosterone testing, and she was licensed to supervise chemistry.[12] P. Br. at 31-32. Petitioner points to CMS's SOD, asserting that, on page one, it indicated that Petitioner's technical consultant and supervisor was '"ZTN" – Zenaida T. Nakar."' P. Br. at 31; CMS Ex. 1, at 1. However, CMS notes that page one of the SOD also lists "PJ" (i.e. Peyman Javaherbin) as a technical consultant and supervisor. Further, Mr. Javaherbin is also listed in the SOD as the "laboratory manager/general supervisor." CMS Ex. 1, at 1; CMS Reply Br. at 22. Thus, as CMS points out, the SOD "correctly lists both Peyman Javaherbin, as well as Zenaida Nakar, as technical supervisor, reflecting the confusion in the laboratory's own records." CMS Reply Br. at 22.

Petitioner contends further that Ms. Nakar's declaration of November 20, 2003, indicates that she was the general and technical supervisor of Petitioner from January 1, 2002 through July 1, 2002. P. Ex. 14, at 168. Surveyor Eleco countered with testimony that the document is "after the fact," given that it is dated November 20, 2003. Tr. 237-38. She stated that the survey of Petitioner was completed on November 7, 2002, and that Ms. Nakar's declaration was part of the plan of correction that Petitioner submitted. Tr. 238.

I note that at the hearing, Mr. Javaherbin denied that he was the supervisor for free testosterone testing. Tr. 354, 355. According to Mr. Javaherbin, Ms. Nakar was the supervisor for free testosterone testing, and was the general and technical supervisor. Tr. 354. He stated that Jerry Lash, a State surveyor, filled out a laboratory personnel report form in 2002 and incorrectly indicated that Mr. Javaherbin, rather than Ms. Nakar, was

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[12] There is some confusion in the record as to the correct spelling of Ms. Nakar's name. In its brief, Petitioner spells her name as "Zeneida Nakar." CMS spells her name as "Zenaida Nakar" in its reply brief. On the laboratory personnel report form, Ms. Nakar's name is spelled as "Zenaida Nakar." P. Ex. 14, at 164. Her statement in her declaration spells her name as "Zenaida Nakkar." P. Ex. 14, at 168.

the supervisor for chemistry.[13] Tr. 354-55; *see* P. Ex. 14, at 166. Mr. Javaherbin stated that he didn't review it and didn't catch Mr. Lash's mistake. Tr. 354-55; *see* P. Ex. 14, at 166.

In examining page 166 of P. Ex. 14, which was completed by Mr. Lash and signed by Petitioner's director on May 30, 2002, I note that both Mr. Javaherbin and Ms. Nakar are listed as the technical consultants in the area of chemistry. By signing the document, Petitioner's director, Iradj Nazarian, certified that all of the individuals listed were qualified to function in the positions indicated, according to the personnel regulations of 42 C.F.R. Part 493 Subpart M. P. Ex. 14, at 166.

CMS further maintains that Petitioner produced no records from the relevant time period that indicated that Ms. Nakar, not Mr. Javaherbin, was Petitioner's technical consultant for chemistry. CMS Reply Br. at 22.

Petitioner did not call Zenaida Nakar to testify and be cross-examined in order to clarify this issue or any other issues relative to the citations in this case. I find that the testimony of Ms. Eleco to be more credible than that of Mr. Javaherbin. I am not persuaded by the declaration of Ms. Nakar, considering that it was prepared over a year after the survey was completed. Thus, I find the testimony and evidence advanced by CMS persuasive in establishing that Mr. Javaherbin was supervising free testosterone testing when he was not qualified to do so. Petitioner's laboratory director, Mr. Nazarian, thus failed to carry out his duty under the regulations to ensure that laboratory personnel possessed the required qualifications.

I conclude that CMS has made a prima facie showing that Petitioner violated each of the above standard-level requirements under the Laboratory Director Condition. Petitioner failed to rebut CMS's prima facie showing by a preponderance of the evidence. These proven standard-level violations constitute a condition-level violation of the Laboratory Director Condition at 42 C.F.R. § 493.1441.

**4. Petitioner was out of compliance with the condition for Quality Assurance at 42 C.F.R. § 493.1701.**

The condition for Quality Assurance at 42 C.F.R. § 493.1701 requires a laboratory performing moderate or high complexity testing to establish and follow written polices and procedures for a comprehensive quality assurance program that is designed to monitor and evaluate the ongoing and overall quality of the laboratory's total testing process. The quality assurance program must evaluate the effectiveness of the

[13] Surveyor Eleco confirmed that Jerry Lash had completed the form. Tr. 238.

laboratory's policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff.

Under this condition, the SOD alleged the following deficiencies: (1) failure to monitor, evaluate, and revise if necessary, based on the results of its evaluations, the usefulness and accuracy of the test report information necessary for the interpretation or utilization of test results (42 C.F.R. § 493.1703(d)); (2) failure to have a mechanism to evaluate corrective actions taken for problems identified during the evaluation of calibration and control data (42 C.F.R. § 493.1705(a)); (3) failure to have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as distribution of patient test results (42 C.F.R. § 493.1711(d)); (4) failure to have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competency (42 C.F.R. § 493.1713); and (5) failure to have a system for verifying the accuracy of its test results at least twice a year, for those tests not enrolled in a proficiency testing program (42 C.F.R. § 493.1709(b)). CMS Ex. 1, at 68-69, 73-74.

CMS has established that Petitioner did not comply with this condition. The evidence demonstrates that Petitioner failed to monitor, evaluate, and revise test report information when necessary. Petitioner failed to detect free testosterone test results that were higher than the upper calibration limit of 50 pg/mL. If Petitioner had an effective quality assurance program in place to monitor and identify problems, it would have detected a trend which indicated extremely high free testosterone results. Petitioner's failure to monitor and evaluate the test results is made even more evident by the fact that Petitioner was not cognizant of the problem, and was only made aware of it after the state surveyor brought it to its attention. *See* Tr. 80-83, 149, 342-43, 376.

Petitioner failed to have a mechanism to evaluate corrective actions taken for problems identified during the evaluation of calibration and control data for free testosterone testing. Petitioner failed to identify the problems with its free testosterone testing, and failed to take corrective action with respect to the free testosterone results beyond the upper limit of the calibration range. Tr. 140. At the survey, Petitioner presented the surveyor with documentation it claimed showed that corrective action had been taken. Tr. 141-42; CMS Ex. 9, at 16, 18. However, the documentation was dated one year prior to the test runs that are the subject of the survey citations. CMS Ex. 9, at 16, 18. Petitioner failed to provide any evidence that any form of corrective action had been taken.

Petitioner also failed to have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as distribution of patient test results. Petitioner submitted no documentation to show that it had evaluated the abnormal free

testosterone results over a three-month period. As stated above, Surveyor Eleco was the one who informed Petitioner that it was using the incorrect data reduction and incorrect calibrator values in its free testosterone testing. E.g., Tr. 149.

In alleging that Petitioner had no mechanism to assure the competency of its staff, CMS points to the supervision and quality control problems that existed. The fact that, during the relevant three-month period, extremely high free testosterone results went unnoticed by Petitioner's testing personnel is further evidence that Petitioner failed to have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence.

Lastly, with respect to verification of its test results, Petitioner was involved in performing tests that were not required to be enrolled in a proficiency testing program. With those tests, Petitioner was required to demonstrate that the accuracy of the test results was verified at least twice a year. CMS alleged that, twice a year, Petitioner took patient specimens, and sent a split of the specimen sample to a referral laboratory performing the same assay by identical methodology. CMS Ex. 1, at 74; Tr. 144-45. However, Petitioner did not provide any documentation that would establish that it compared and analyzed the results from its own internal test runs with the results of test runs performed at the outside laboratory. Tr. 147-48. Petitioner thus failed to establish that it had in place a system for verifying the accuracy of its test results at least twice a year.

What is apparent from these cited failures, which extended over a period of time, is that Petitioner was deficient in applying any quality control policies to identify and correct erroneous testing practices. This demonstrates that neither Petitioner's quality control or quality assurance programs were effective and that Petitioner's testing personnel, the general supervisor, technical supervisor, and the laboratory director all failed in their responsibilities to perform tests competently as required by the regulations.

I conclude that CMS made a prima facie showing that Petitioner violated each of the above standard-level requirements under the Condition for Quality Assurance. I find that Petitioner failed to rebut CMS's prima facie showing by a preponderance of the evidence. I conclude further that these proven standard-level deficiencies amount to a condition-level violation of the condition for Quality Assurance at 42 C.F.R. § 493.1701.

**B. Petitioner was also in violation of the following conditions: Condition for Technical Supervisor, at 42 C.F.R. § 493.1447; Condition for General Supervisor, at 42 C.F.R. § 493.1461; and Condition for Testing Personnel, at 42 C.F.R. § 493.1487.**

The SOD also alleges that Petitioner violated the Technical Supervisor Condition at 42 C.F.R. § 493.1447; the General Supervisor Condition at 42 C.F.R. § 493.1461; and the Testing Personnel Condition at 42 C.F.R. § 493.1487. CMS Ex. 1, at 59-68. With respect to the Technical Supervisor condition, the SOD alleges that Petitioner's technical supervisor failed to establish a quality control program appropriate for the testing performed and failed to establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. CMS Ex. 1, at 59-60. The findings in support of this deficiency center on Petitioner's free testosterone testing, and the technical supervisor's failure to have an appropriate quality control program. The SOD alleged that the controls used by the laboratory failed to monitor the extremely high free testosterone results obtained and reported, and the technical supervisor failed to establish parameters for acceptable assay calibration. CMS Ex. 1, at 61-64.

I have previously determined that Petitioner was out of compliance with the Condition for General Quality Control at 42 C.F.R. § 493.1201 and Condition for Quality Assurance at 42 C.F.R. § 493.1701. I found that there was an absence of oversight and that Petitioner was deficient in the areas of quality control and quality assurance. Accordingly, those condition-level violations also lead to the conclusion that Petitioner violated the Condition for Technical Supervisor at 42 C.F.R. § 493.1447.

The SOD alleges a violation of the General Supervisor Condition at 42 C.F.R. § 493.1461 based on Petitioner's failure to have a general supervisor who was authorized to supervise high complexity testing in chemistry under state law, and the general supervisor's failure to provide day-to-day supervision of high complexity test performance by testing personnel. CMS Ex. 1, at 64. As discussed above, the evidence showed that Mr. Peyman Javaherbin was Petitioner's general supervisor at the time of the survey. I found that Mr. Peyman Javaherbin was supervising free testosterone testing, which is classified under the specialty of chemistry, in the subspecialty of endocrinology. However, because he possessed a license that was limited to microbiology, Mr. Javaherbin was not authorized to supervise high complexity testing in chemistry under California state law. By supervising in chemistry, Mr. Javaherbin was supervising outside the scope of his microbiologist's license.

I have previously found that Petitioner was in violation of the Conditions pertaining to General Quality Control at 42 C.F.R. § 493.1201 and Endocrinology at 42 C.F.R § 493.1247. Under those conditions, I discussed Petitioner's problems in free testosterone testing and reporting. Those problems leave no doubt that Petitioner's general supervisor failed to provide day-to-day supervision of high complexity testing by test personnel. I conclude that Petitioner violated the General Supervisor Condition at 42

C.F.R. § 493.1461, and that Petitioner did not rebut CMS's prima facie showing by a preponderance of the evidence.

With respect to the Condition for Testing Personnel at 42 C.F.R. § 493.1487, the SOD alleges that Petitioner's testing personnel failed to identify problems that affected test performance or reporting of results, and failed to either correct the problems or notify the general supervisor, clinical consultant, or director. CMS Ex. 1, at 66-67. As support for this condition-level deficiency, the SOD refers to the problems with the free testosterone testing. CMS Ex. 1, at 67-68. I have already discussed at length how Petitioner's testing personnel failed in several ways with respect to free testosterone testing. My conclusion that CMS established condition-level violations in General Quality Control and Endocrinology also lead to the conclusion that Petitioner was out of compliance with the Condition for Testing Personnel at 42 C.F.R. § 493.1487.

### C. Because Petitioner was out of compliance with one or more conditions, CMS is authorized to impose sanctions.

Petitioner has argued, in essence, that CMS is making a "mountain out of a molehill." CMS, Petitioner argues, has elevated a simple case of noncompliance regarding minor deficiencies to a matter which will result in the revocation of its CLIA certificate. However, Petitioner has provided no authority or evidence in the statute or the regulations that supports its view that citations are only warranted for "major" deficiencies. Although it admits to instances of noncompliance, Petitioner attempts to limit its culpability by arguing that the noncompliance is minor in nature and no patients were harmed as the result of the deficiencies. In many instances, Petitioner has not even attempted to address the survey citations, let alone advance a defense to establish that it was in compliance. I find that Petitioner provides no basis in the law, case law, or facts that supports its equitable argument that it is improper for CMS to impose a CMP, suspend Medicare payments, and revoke Petitioner's CLIA certificate in this case.

According to Petitioner, CMS is using problems with one test system as a basis to cite violations of 15 standard-level and condition-level deficiencies. However, as CMS has established, the standard-level and condition-level deficiencies which arose out of the free testosterone test assay are demonstrative of a larger systemic failure of the laboratory. The citations stemming from the failures with the free testosterone test assay demonstrate that Petitioner did not, or could not, follow manufacturer's instructions relative to the tests; that laboratory testing personnel failed to notice a problem with the test despite clearly high results; and that testing personnel failed to analyze and review test results for accuracy and reliability. The citations, along with the other deficiencies, further demonstrate that Petitioner's quality control programs and quality assurance programs were ineffective, and testing personnel, the general supervisor, the technical supervisor,

and the laboratory director all failed in their responsibilities to perform tests accurately and reliably.

CMS has sustained its burden of proving that Petitioner failed to comply with one or more condition-level CLIA requirements. Because Petitioner had at least one condition-level deficiency, CMS may impose sanctions. 42 C.F.R. § 493.1804(b); *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999). Petitioner's condition-level violations fully support CMS's determination to revoke Petitioner's CLIA certificate. Furthermore, CMS has established a legal basis for the cancellation of Petitioner's ability to receive Medicare payments for laboratory services, as well as providing a basis for the imposition of a $3,000 per day CMP. 42 C.F.R. §§ 493.1806(b); 493.1806(c)(3), 493.1807(a); 493.1808(a); 493.1834; and 493.1842(a).

## V. Conclusion

Having sustained CMS's revocation of Petitioner's CLIA certificate, I further find that Mr. Peyman Javaherbin and Dr. Iradj Nazarian are prohibited from owning or operating a CLIA laboratory for two years in accordance with 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8).

/s/

Alfonso J. Montano
Administrative Law Judge