

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2051292	(X3) Date Survey Completed 10/19/2023
Name of Provider or Supplier Anesthesiology Coagulation Laboratory	Street Address, City, State 111 South 11th Street, Philadelphia, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, College of American Pathologists (CAP) proficiency testing (PT) records, and interview with the laboratory director (LD), the laboratory failed to provide 1 of 2 attestation statements for hematology testing events performed in 2022. Findings Include: 1. The Anesthesiology Coagulation Laboratory Policies & Procedures (page 10) states, " All result entry forms, instrument printouts, electronic forms, the Attestation Form and other related PT documentation are posted in the CAP Surveys binder. PT documentation is retained for atleast two years after the initial PT test date." 2. On the day of the survey, 10/19/2023 at 11:34 am, the laboratory could not provide 1 of 2 CAP PT attestation statements for the following hematology testing events in 2022: - CAP Viscoelastic Studies (VES-B 2022) 3. The LD confirmed the finding above on 10/19/2023 at 01:00 pm.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p>

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's competency assessment records and interview with the laboratory director (LD), the laboratory failed to establish a competency assessment procedure to assess the competency of 1 of 2 clinical consultants (CC) for their supervisory responsibilities in 2022. Findings include: 1. On the day of the survey, 10/19/2023 at 10:51 am, the laboratory could not provide a competency assessment policy to assess the competency of the following personnel for their supervisory responsibilities in 2022: - 1 of 2 CC (CMS 209 CC #2) 2. The laboratory could not provide competency assessment documentation for 1 of 2 CC (CMS 209 CC #2). 3. The LD confirmed the findings above on 10/19/2023 at 01:00 pm.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures, College of American Pathologists (CAP) proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to verify the accuracy of the PT results obtained for 3 of 3 CAP hematology testing events reviewed for 2022 and 2023. Findings include: 1. The Anesthesiology Coagulation Laboratory Policies & Procedures (page 11) states, " It is the responsibility of the Director to evaluate results obtained from PT challenges that were intended to be graded, but were not." 2. On the day of survey, 10/19/2023 at 11:34 am, review of the laboratory's CAP PT records revealed that the laboratory did not verify the accuracy for the following 3 of 3 CAP hematology testing events for 2022 and 2023 that were not graded by the PT agency: - Viscoelastic Studies - VES A 2023 - VES B 2022 - VES A 2022 3. The CAP's actions laboratories should take when a PT result is not graded document states, "the laboratory is required to review participant summary for comparative results and document performance accordingly. Evaluation criteria is not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 4. The LD confirmed the findings above on 10/19/2023 at 01:00 pm

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The

laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Individualized Quality Control Plan (IQCP) and interview with the laboratory director (LD), the laboratory failed to provide a complete IQCP for activated clotting time (ACT) testing performed on the Werfen Rotem from 11/17/2021 to the day of the survey. Findings include: 1. On the day of the survey, 10/19/2023 at 12:06 pm, review of the laboratory's individualized quality control plans revealed that the laboratory failed to provide a complete IQCP for the following tests: - 1 of 3 parts of the IQCP for ACT (hematology) testing performed on the Werfen Rotem were incomplete: no documentation provided for the quality control plan. 2. The LD confirmed the findings above on 10/19/2023 at 01:00 pm.

D5463

CONTROL PROCEDURES

CFR(s): 493.1256(d)(7)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
Over time, rotate control material testing among all operators who perform the test.
(g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) records and interviews with the laboratory director (LD) and testing personnel (TP) #3, the laboratory failed to over time rotate control material testing between 7 of 8 TP who performed activated clotting time (hematology) testing on the Werfen Rotem analyzer from 01/01/2022 to 10/19/2023. Findings include: 1. On the date of the survey, 10/19/2023 at 11:45 am, review of the laboratory's QC records for the Werfen Rotem analyzer revealed that 7 of 8 TP (CMS 209 TP #1, #2, #4, #5, #6, #7, and #8) failed to perform QC for activated clotting time testing performed from 01/01/2022 to 10/19/2023. 2. The LD and TP #3 confirmed the findings above on 10/19/2023 at 01:00 pm.

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of patient test reports and interview with the laboratory director (LD), the laboratory failed to include pertinent reference intervals/normal values on patient test reports for activated clotting time (ACT) examinations performed on the Werfen Rotem analyzer in October 2023. Findings Include: 1. On the day of the survey, 10/19/2023 at 12:50 pm, review of 2 of 2 patient reports revealed that the laboratory failed to include pertinent reference intervals/normal values on the final reports for ACT examinations performed in October 2023 on the Werfen Rotem. 2. The LD confirmed during an interview on 10/19/2023 at 01:00 pm, that the computer system was updated recently and the reference intervals/normal ranges were no longer listed on the patient reports. .

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedures, training and competency assessment records, and interview with the laboratory director (LD), the technical consultant (TC) failed to evaluate and document the performance of 1 of 8 testing personnel (TP) responsible for performing activated clotting time (hematology) examinations for their semi-annual competency from 08/03/2021 to the day of survey. Findings include: 1. The laboratory's Anesthesiology Coagulation Laboratory Policies and Procedures (page 6) states, "Competency assessment is conducted by the AC laboratory specialists: after initial user training, six months after the user has performed the first patient test, twelve months after the user has performed the first patient test, and annually thereafter. Training and competency assessment documentation is maintained by the AC Laboratory Specialists. The documentation is maintained for the duration of the tester's employment." 2. On the day of survey, 10/05/2022 at 10:15 am, the laboratory could not provide the semi-annual competency assessment records for 1 of 8 TP (CMS 209 TP # 2) that performed activated clotting time (hematology) examinations on the Werfen Rotem analyzer from 08/03/2021 to 10/19/2023. 3. The LD confirmed the findings above on 10/19/2023 at 01:00 pm.