

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2136938	(X3) Date Survey Completed 12/10/2019
Name of Provider or Supplier College Park Medical Center	Street Address, City, State 4701 Melbourne Place, College Park, MD	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to test PT samples in the same manner as patient samples. Findings: 1. American Proficiency testing (API) 2019 1st event Hematology attestation and performance review were signed by the laboratory director and the testing person on 3/28/2019. 2. PT samples were ran on 3/20/2019 and samples 1/3 were ran twice. 3. The TC stated that if they have problems with patients samples they run them twice but the TC did have a written procedure stating that patient samples are ran twice when problems arise. 4. The TC was unable to explain why the attestation and the performance review were completed and signed on the same date.</p>
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</p>

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.

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to have all copies of PT records that were obtained when performing PT. Findings: 1. The laboratory did not have the American Proficiency testing (API) 2019 2nd event Hematology attestation signed by the appropriate staff that performed the PT testing. 2. The TC confirmed that the API 2019 2nd event Hematology attestation was not available 3. The laboratory did not have raw data, attestation, nor performance review for the API 2018 3rd event Hematology. 4. The TC confirmed that the API 2018 3rd event Hematology raw data, attestation, nor performance review was available

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to review proficiency testing results. Findings: 1. The laboratory did not have the American Proficiency testing (API) 2019 2nd and 3rd event Hematology performance review reviewed and signed by the appropriate staff. 2. The TC confirmed that the API 2019 2nd and 3rd event Hematology performance review was not available.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on review of the written procedure manual and interview with the technical consultant (TC), the laboratory did not have a written proficiency testing (PT) procedure. Findings: 1. The laboratory did not have a written proficiency testing procedure with step by step instructions for the testing personal to follow when performing PT. 2. The TC confirmed that a written PT procedure was not available.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) records and interview with the technical consultant (TC), the laboratory failed to document corrective procedures when hematology QC did not meet the laboratory's criteria of acceptability. Findings: 1. On November 6, 2019 the low QC was out. The testing person did not document corrective action procedures showing the steps taken when the error occurred. 2. The TC confirmed that corrective action procedures were not documented.

D5803

TEST REPORT

CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:

Based on review of patient test logs, final reports, and interview with the technical consultant (TC) and the testing person (TP), the laboratory failed to have all patient final test results available on the day of the survey. Findings: 1. On October 4, 2018 the laboratory ran a CBC (complete blood count) on patient "A" that was not documented on the patient log book but ordered in the EMR. The sample was run twice according to the patient log transcription but a final result was not available in the electronic medical record (EMR). 2. On May 14, 2018 the laboratory ran a CBC on patient "A" it was documented as a "control sample" in the patient log book and the final result was not available in the EMR. 3. On May 4, 2018 the laboratory ran a CBC on patient "B" it was documented in the patient log book that it was sent to a reference lab for differential testing. The final in house result was not available in the EMR. 4. The TC and the TP could not explain why the final CBC result was not available in the patient EMR nor the meaning of "control sample".

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director

review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual and interview with the technical consultant (TC), the laboratory director failed to establish delegation responsibilities for laboratory staff. Findings: 1. The attestation page for the American Proficiency testing (API) 2019 3rd event Hematology was signed by the testing person in the laboratory director section and also in the section for the testing person. 2. The TC stated that the testing person may have signed in the wrong section of the attestation page.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

I. Based on review of quality control (QC) records, review of the corrective action log, and interview with the technical consultant (TC), the TC failed to oversee all technical and scientific areas of the laboratory. Findings: 1. On April 9, 2019 the startup on the hematology analyzer failed multiple times and was restarted eight times prior to running patient samples. 2. Tech support was never called to come in for service on the hematology analyzer during the time the startup was failing. 3. The TC was not aware of the corrective action log and reviews were not performed on the log between 2018 and 2019. II. Based on review of the written procedure manual and interview with the technical consultant, the TC failed to ensure that testing personnel followed the written procedure when performing QC for hematology testing.

Findings: Refer to D6070

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the TC failed to ensure that PT records and documentation meet the laboratory's criteria of acceptability. Findings Refer to D2006, D2015, and D5211

D6043

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(5)

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

This STANDARD is not met as evidenced by:
Based on review of quality control records and interview with the technical consultant (TC), the TC failed to ensure that corrective procedures were documented when hematology QC did not meet the laboratory's criteria of acceptability. Findings: Refer to D5781

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on review of the written procedure manual and interview with the technical consultant (TC), testing personnel failed to follow the written procedures when performing quality control (QC) for hematology testing. Findings: 1. The QC procedure states that when hematology QC is out to repeat once and if still out to contact tech support. 2. On November 6, 2019 the low QC was out and repeated three times. 3. On April 21, 2019 the high QC was out and repeated four times. 4. On April 13, 2019 the normal QC was out and repeated three times. 5. On April 8, 2019 the low QC was out and repeated three times. 6. On each date that QC was repeated more than once tech support was not called and a service report was not available. 7. The TC stated that tech support was called but was not documented by the testing personnel. 8. The TC never performed consultations and retraining of TP.