

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405602	(X3) Date Survey Completed 04/16/2021
Name of Provider or Supplier Olivia Hospital & Clinic	Street Address, City, State 100 Healthy Way, Olivia, MN	
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one 2019 non-graded proficiency testing (PT) result for a regulated analyte when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor during a tour of the laboratory at 1:05 p.m. on 04/15/21. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. One Microbiology result from the first 2019 Microbiology PT event was not graded by API. See below. Sample ID Test UR-01 MIC/Cefuroxime 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summary for the above analyte was not present in laboratory records. Evaluation of the non-graded result was not found in laboratory records. 5. Investigation of non-graded PT results was required as established in the laboratory's Proficiency Testing Procedure. The laboratory was unable to provide an evaluation of the non-graded result upon request. 6. In an interview at 4:30 p.m. on 04/15/21, the Technical Consultant confirmed the above finding. .</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance</p>

(that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one 2019 non-graded proficiency testing (PT) result for a non-regulated analyte when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor during a tour of the laboratory at 1:05 p.m. on 04/15/21. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. One Hematology result from the third 2019 Hematology PT event was not graded by API due to lack of consensus. See below. Sample ID Analyte COU-12 Nucleated Red Blood Cells 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summary for the above analyte was not present in laboratory records. Evaluation of the non-graded result was not found in laboratory records. 5. Investigation of non-graded PT results was required as established in the laboratory's Proficiency Testing Procedure. The laboratory was unable to provide an evaluation of the non-graded result upon request. 6. In an interview at 4:30 p.m. on 04/15/21, the Technical Consultant confirmed the above finding. .

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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) activities as established in a Toxicology Individualized Quality Control Plan (IQCP) in 1 of 24 weeks reviewed . Findings are as follows: 1. The laboratory performed Toxicology testing as confirmed by the General Supervisor during a tour of the laboratory at 1:05 p.m. on 04/15/21. 2. A MedToxScan toxicology analyzer was observed as present and available for use during the tour. 3. MedToxScan QC performance was required weekly as established in the Profile-V Medtox Scan Drugs of Abuse procedure and in the laboratory's IQCP for the test, both found in laboratory procedure manuals. 4. The laboratory exceeded the weekly time interval for QC performance in 1 of 24 weeks reviewed; April - September 2020. The omission potentially affected 1 patient (Pt)test result. See below. QC date Pt test date Days elapsed 03/30/20 04/07/21 8 5. In an interview at 1:25 p.m. on 04/16/21, the Technical Consultant confirmed the above finding.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Technical Supervisor (TS) failed to ensure 3 of 3 new testing personnel (TP) received documented training for 2 of 13 testing platforms in use by the laboratory. In addition, the TS failed to ensure 6 of 6 TP in 2019 and 4 of 6 TP in 2020 received documented annual competency assessments for all test procedures performed under the Microbiology, Immunology, Chemistry, Hematology, and Immunohematology specialties. Findings are as follows: A. Training 1. The laboratory performed Urine Drug Screens and Microscopic Examinations (Urine Sediment, Manual White Blood Cell Differential, KOH Wet Preparation and Post Vasectomy) as confirmed by the General Supervisor during a tour of the laboratory at 1:05 p.m. on 04/15/21. 2. Testing personnel 5 (TP5) was hired in June 2019, and TP1 and TP2 were hired in March and May and 2020, respectively, as indicated in laboratory records. 3. The laboratory's New Hire Lab Orientation Policy indicated TP were trained on all policies and procedures prior to testing patient specimens. 4. Initial training documentation for the above tests for TP1, TP2, and TP3 was not found during review of laboratory personnel records. The laboratory was unable to provide the missing document upon request. 5. In an interview at 3:30 p.m. on 04/15/21, the Technical Consultant confirmed the above finding. B. Annual Competency Assessments 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology as confirmed by the GS during a tour of the laboratory 1:05 p.m. on 04/15/21. 2. The laboratory's Competency Assessment Procedure indicated TP were evaluated annually for competency in all tests performed. The Annual Employee Competencies document, found in the procedure and used to record TP competency, included the six required elements for competency evaluation as indicated at 493.1451. 3. The single page Annual Employee Competencies document was completed for each TP in 2019 and 2020 to cover the entirety of testing performed by the laboratory. The document did not provide evidence that each area of testing was evaluated during the annual competency assessments. 4. In an interview at 3:30 p.m. on 04/15/21, the Technical Consultant confirmed the above finding. .

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

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

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Technical Supervisor failed to ensure 3 of 3 new testing personnel (TP) were evaluated for competency in 12 of 13 testing platforms in use by the laboratory at least semiannually during the first year of patient specimen testing. Findings are as follows:

1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunochemistry as confirmed by the General Supervisor during a tour of the laboratory at 1:05 p.m. on 04/15/21. 2. TP5 was hired in June 2019, and TP1 and TP2 were hired in March and May and 2020, respectively, as indicated in laboratory records. 3. The laboratory's New Hire Lab Orientation Policy indicated TP were evaluated for competency in all testing areas semi-annually during the first year of patient testing. The 6 Month Post Hire Competencies: Tech document, found in personnel records and used to record the semi-annual competency, included a separate line for listed departments with an area to record competency in each. The document did not include the six required competency elements indicated at 493.1451. 4. The single page 6 Month Post Hire Competencies: Tech document was completed for TP5 in 2019 and TP1 and TP2 in 2020 to cover the entirety of testing performed by the laboratory. The document did not provide evidence that the evaluation of each area of testing included the six required competency elements. Acceptable semi-annual coagulation competency assessment for TP5, TP1, and TP2 were found. 5. In an interview at 3:30 p.m. on 04/15/21, the Technical Consultant confirmed the above finding. .