

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405602	(X3) Date Survey Completed 12/15/2022
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to retain Hematology quality control records and Chemistry analyzer maintenance records for at least 2 years. Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the Senior Laboratory Manager (SLM) and Testing Personnel 4 (TP4) during a tour of the laboratory at 10:05 a.m. on 12/07/22. A. Chemistry 1. An Abbott Architect ci4100 chemistry analyzer was observed as present and available for use during the tour of the laboratory. 2. Analyzer maintenance was required by the manufacturer and was driven by onboard software. 3. Architect maintenance reports from October 2021 were not found on date of survey, 12/08/22. The laboratory was given five days to provide the missing documents. 4. In an interview at 2:30 p.m. on 12/08/22, TP4 confirmed the above finding. 5. In an email received at 10:35 a.m. on 12/15/22, the SLM indicated the requested Architect analyzer maintenance records were not available. B. Hematology 1. A Beckman Coulter DxH600 hematology analyzer was observed as present and available for use during the tour of the laboratory. 2. Quality Control (QC) testing was performed daily as established in the Beckman Coulter DxH600 procedure found in C360, the laboratory's electronic procedure software. 3. QC records from July through September 2021 were not found on date of survey, 12/08/22. 4. In an interview at 12:15 p.m. on 12/08/22, TP4 confirmed the above finding. TP4 indicated QC records were retained in the analyzer and the analyzer held only one year of data. .</p>

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure 22 of 41 Chemistry reportable ranges and 3 of 3 Hematology (Coagulation) reportable ranges obtained during performance verification (PV) activities completed in 2021 and 2022 were adopted by the laboratory. Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the Senior Laboratory Manager (SLM) and Testing Personnel 4 (TP4) during a tour of the laboratory at 10:05 a.m. on 12/07/22. A. Chemistry 1. An Abbott Architect ci4100 chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began using this analyzer to perform testing in September 2021 as confirmed by the TP4 during the tour. 2. PV activities were completed in August 2021 as indicated in laboratory records found in the Integration Binder IACC ilsr65222 and Integration Binder IACC c403018 manuals. The Laboratory Director approved the PV on 08/30/21. 3. The upper and/or lower reportable range limits adopted by the laboratory for 22 of 41 analytes did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in the PV documents, the Abbott Immunoassay Reportable and Reference Range Summary, and Abbott Clinical Chemistry Reportable and Reference Range Summary. See below. Analyte PV Adopted Procalcitonin 0.0-96.17 0.05-100 Acetaminophen 0.37-275.4 3-337 Albumin 0.6-9.3 0.4-6.0 ALT 8.8-3409.4 10-4000 AST 4.5-3862.6 5-4000 Bili, Total 0.01-17.3 0.1-22.0 Calcium 0.02-17.9 1.0-24.0 Creatine Kinase 10.9-4306.6 10-4000 Chloride 54.4-142.0 55-145 CrEnz 0.19-35.04 0.1-35 ETOH 0.0001-0.427 0.01-0.6 Potassium 1.1-9.6 1.0-9.5 Lactic Acid 0.01-9.81 0.2-13.4 Magnesium 0.0-7.1 0.7-8.5 Sodium 107.8-189.9 105-180 Salicylate 0.29-71.8 5-90 Total Protein 1.1-12.7 1-17 Triglyceride 11.3-1336.6 5-1350 Uric Acid 0.003-22.1 1-28 HDL 0.0-129.9 5-145 Urine Protein 0.13-81.5 1-200 Urea 3.8-117.4 5-120 4. In an interview at 10:20 a.m. on 12/08/22, the SLM confirmed the above finding. B. Hematology 1. A Stago Satellite coagulation analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began using this analyzer to perform the following tests in May 2022 as indicated by TP4 during the tour. Prothrombin Time (PT) Activated Partial Thromboplastin Time (aPTT) D-Dimer (DD) 2. PV activities on the Satellite analyzer were completed in May 2022 as indicated in laboratory records found in the Satellite Validation manual. The Laboratory Director approved the PV on 05/13/22. 3. The PT, aPTT, and DD lower and/or upper reportable range limits adopted by the laboratory did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in the PV documents. See below. Analyte PV Adopted PT 13.0->100 10-100 aPTT 28.4->180 20-180 DD 0.38-18.49 0.27-20 4. In an interview at 9:05 a.m. on 12/08/22, the SLM confirmed the above finding. .

D5431

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure function checks for a Chemistry analyzer were performed and documented as required in 2021 and 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Senior Laboratory Manager (SLM) and Testing Personnel 4 (TP4) during a tour of the laboratory at 10:05 a.m. on 12/07/22. 2. An i-STAT analyzer was observed as present and available for use during the tour. The laboratory used the i-STAT analyzer for Blood Gas testing and as a back-up method for Basic Metabolic Panel and Creatinine testing. 3. Twice annual verification of the i-STAT thermal probe was required as established in the Abbott i-STAT Analyzer procedure found in the C360 procedure program. 4. Thermal probe check documentation from 2021 and 2022 was not found in laboratory records. The laboratory was unable to provide this documentation upon request. 5. In an interview at 3:00 p.m. on 12/08/22, TP4 confirmed the above finding and indicated the thermal probe check had not been performed in 2021 and 2022. .

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document maintenance and function check activities for general laboratory equipment in 2021 and 2021. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the Senior Laboratory Manager (SLM) and Testing Personnel 4 (TP4) during a tour of the laboratory at 10:05 a.m. on 12/07/22. 2. Thermometers and timers were observed in the laboratory as present and available for use during the tour. 3. Annual thermometer and quarterly timer function checks were required as established in the Preventative Maintenance procedure found in the laboratory's electronic procedure program C360. 4. Thermometer and timer maintenance and function check documentation for 2021 and 2022 was not found during review of laboratory records. The laboratory was given five days to provide the missing documentation. 5. In an interview at 4:15 p.m. on 12/08/22, TP4 confirmed the above findings. 6. In an email received at 10:35 a.m. on 12/15/22, the SLM indicated the requested thermometer and timer function check records were not available. .

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 Chemistry Individualized Quality Control Plan (IQCP) for 17 patient specimens tested in 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Senior Laboratory Manager (SLM) and Testing Personnel 4 (TP4) during a tour of the laboratory at 10:05 a.m. on 12/07/22. 2. A MedToxScan device and Profile V test kits were observed as present and available for use during the tour. 3. QC performance using two levels of control material was required weekly as established in the Drugs of Abuse Screen for Urine Procedure found in the C360 electronic procedure program and in the laboratory's IQCP for the test. 4. The laboratory exceeded the weekly QC performance time interval for 17 patient specimens tested in the time frame reviewed, March through May of 2022, as indicated in laboratory records. See below. QC date QC due QC performed 03/20/22 03/27/22 04/11/22 10 patient specimens were tested between 03/27/22 and 04/10/22 QC date QC due QC performed 04/11/22 04/18/22 04/22/22 7 patient specimens were tested between 04/18/22 and 04/21/22 5. In an interview at 12:55 p.m. on 12/08/22, TP4 confirmed the above finding. .

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to follow the Quality Assessment Plan (QAP) for four of four Individualized Quality Control Plans (IQCP) developed by the laboratory. Findings are as follows: 1. The laboratory performed Microbiology and Chemistry testing as confirmed by the Senior Laboratory Manager (SLM) and Testing Personnel 4 (TP4) during a tour of the laboratory at 10:05 a.m. on 12/07/22. 2. The laboratory performed patient specimen testing using the tests or test systems listed below as confirmed by the TP4 during the tour. Molecular testing via Meridian Alethia platform Blood gas via Abbott i-STAT analyzer MedToxScan Profile-V urine drug screen device Meridian Serum hCG test kit 3. The laboratory implemented IQCP's for the above listed tests or test systems to reduce quality control requirements. The QAP for each

of the IQCP's indicated the IQCP would be reviewed annually. 4. Documentation of 2021 annual IQCP review was not present in laboratory records. The laboratory was unable to provide documentation of IQCP quality assessment review from 2021 upon request. 5. In an interview at 11:45 a.m. on 12/08/19, TP4 confirmed the above finding. .

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the Laboratory Director failed to ensure one of one new testing personnel and two of two tenured testing personnel were evaluated for test procedure competency in 2021 as required. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunochemistry testing as confirmed by the Senior Laboratory Manager (SLM) and Testing Personnel 4 (TP4) during a tour of the laboratory at 10:05 a.m. on 12/07/22. 2. The laboratory was cited for non-performance of initial and annual competency evaluations during the previous survey conducted on 04/16/21. 3. An initial competency evaluation was found incomplete on date of current survey, 12/07/22, for one of one new testing personnel hired in 2021. Annual competency evaluations were found incomplete on date of current survey for two of two tenured testing personnel. See D6120. 4. The laboratory was cited for non-performance of semi-annual competency evaluations during the previous survey conducted on 04/16/21. 5. A semi-annual competency evaluation was not found on date of current survey for one of one testing personnel hired in 2021. See D6127. 6. In an interview at 3:20 p.m. on 12/07/22, the SLM 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 failed to ensure comprehensive initial training for one of one new testing personnel (TP) and comprehensive annual competency assessment for two of two tenured TP was performed and documented in 2021. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunochemistry testing as confirmed by the Senior Laboratory Manager (SLM)

and Testing Personnel 4 (TP4) during a tour of the laboratory at 10:05 a.m. on 12/07/22. 2. The following tests were performed by the laboratory in 2021 as indicated by TP4 during the tour: Molecular testing via Alethia platform (MOL) Chemistry via AU480 platform (CHEM) Blood gas via i-STAT platform (BG) MedToxScan Profile-V urine drug screen (UDS) Hematology via DxH600 platform (CBC) Manual differential (Diff) Coagulation via CA-600 platform (COAG) Immunohematology (IH) KOH microscopic examination (KOH) Vaginal wet preparation examination (VWP) Urine Sediment examination (US) Post vasectomy semen analysis (PV) Amnisure ROM (ROM) Serum hCG (hCG) 3. Personnel competency evaluation was required after training and annually as established in the New Hire Lab Orientation procedure and Competency Assessment Policy found in the C360 electronic procedure program. 4. Comprehensive initial training documentation was not found during review of TP6's personnel records as listed below. Training records not found CHEM, BG, UDS, US, PV, COAG, IH 5. Comprehensive annual competency assessments were not found during review of personnel records for the following testing personnel: TP4 and TP10. See below Test TP missing training records MOL TP4, TP10 UDS TP4, TP10 CBC TP10 Diff TP4, TP10 COAG TP10 IH TP4, TP10 KOH TP4, TP10 VWP TP4, TP10 US TP4, TP10 PV TP4, TP10 ROM TP10 hCG TP10 6. The laboratory was unable to provide the missing training records and missing competency assessment documents upon request. 7. In an interview at 3:20 p.m. on 12/07/22, the SLM 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 document review and interview with laboratory personnel, the Technical Supervisor failed to complete a competency assessment at least semi-annually during the first year of patient specimen testing for one of one testing personnel hired in 2021. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the Senior Laboratory Manager (SLM) and Testing Personnel 4 (TP4) during a tour of the laboratory at 10:05 a.m. on 12/07/22. 2. The following non-waived test systems, analyzers, devices, and test kits were in use in 2021 as indicated by TP4 during the tour: Meridian Alethia molecular platform Beckman Coulter AU480 chemistry analyzer Beckman Coulter Access 2 chemistry analyzer Abbott i-STAT device MedToxScan Profile-V urine drug screen analyzer Beckman Coulter DxH600 hematology analyzer Sysmex CA-600 coagulation analyzer Quidel Triage Meter Meridian Alethia molecular platform Grifols Immunohematology test system Microscopes for microscopic examinations Amnisure ROM test kit Serum hCG test kit 3. Personnel competency evaluation was required six months after hire as established in the New Hire Lab Orientation procedure and Competency Assessment Policy found in the C360 procedure program. 4. Initial training was performed and documented for TP6 in April through July 2021 as indicated in personnel records. Training was not documented for seven tests and/or test systems. See D6120 5. Semi-annual competency assessment documentation for TP6 was not found in personnel records. 6. The laboratory was unable to provide the missing documents upon request. 7. In an interview at 3:20 p.m. on 12/07/22, the SLM confirmed the above finding. .