

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2131019	(X3) Date Survey Completed 10/18/2019
Name of Provider or Supplier Axis Clinicals Llc	Street Address, City, State 1711 Center Ave W, Dilworth, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director or designee and Testing Personnel failed to attest to the integration of proficiency testing samples into the routine patient workload on one occasion in 2018 and 4 occasions in 2019. Findings are as follows: 1. The laboratory performed Chemistry, Toxicology, Endocrinology, Urinalysis, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/18/19 at 8:25 a.m. 2. The laboratory performed proficiency testing (PT) using the College of American Pathologists (CAP) PT provider. 3. The Laboratory Director and Testing Personnel were required to sign the attestation statements as established in the Proficiency Testing procedure located in the Toxicology & Clinical Laboratory Personnel Quality Assessment manual. 4. The Laboratory Director or designee and Testing Personnel failed to attest to the integration of PT samples into the routine patient workload for 1 of 11 CAP PT events in 2018, and 4 of 18 CAP PT events in 2019. See below. Year Event 2018 Chemistry - C 2019 Urine Drug Adulterant /Integrity Testing - B Viral Markers - B Urine Drug Confirmation - B Urine Drug Confirmation - C 5. In an interview on 10/18/19 at 12:30 p.m., the GS confirmed the above finding. .</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to establish a written competency assessment procedure which included the following requirements found in Subpart M, and failed to establish a competency assessment process / documentation form for the testing areas of Hematology and Drugs of Abuse Confirmatory Testing. 493.1451 (b)(8)(i) Direct observation of routine test performance; (b)(8)(ii) Monitoring the recording and reporting of test results; (b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records; (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks; (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and (b)(8)(vi) Assessment of problem solving skills. Findings are as follows: 1. The laboratory performed Chemistry, Toxicology, Endocrinology, Urinalysis, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/18/19 at 8:25 a.m. 2. A competency assessment procedure was not found during review of laboratory policies and procedures. The laboratory was unable to provide a competency assessment procedure upon request. 3. A documentation system for recording the competency assessment of personnel performing testing in the areas of Hematology and Drugs of Abuse Confirmatory Testing was not found. The laboratory was unable to provide the competency assessment documentation forms upon request. 4. In an interview on 10/18/19 at 10:45 a.m., the GS confirmed the above finding. .

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 document review and interview with laboratory personnel, the laboratory failed to review and evaluate proficiency testing (PT) results for 4 of 11 events in 2018 and 6 of 18 events in 2019. Findings are as follows: 1. The laboratory performed Chemistry, Toxicology, Endocrinology, Urinalysis, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/18/19 at 8:25 a.m. 2. The laboratory performed proficiency testing (PT) using the College of American Pathologists (CAP) PT provider. 3. Results of the following PT events were found in the laboratories records. Evidence that these results were reviewed or evaluated by the laboratory was not found. Year Survey / Event 2018 Urine Drug Adulterant/Integrity Testing - B Urine Drug Screen - C Urine Drug Confirmation - C Urine Drug Confirmation - D 2019 Urine Drug Adulterant/Integrity Testing - B Viral Markers - B Urine Drug Screen - B Urine Drug Confirmation - A Urine Drug Confirmation - B Urine Drug Confirmation - C 4. In an interview on 10/18/19 at 12:30 p.m., the GS confirmed the above finding. .

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory director failed to ensure proficiency testing (PT) results were evaluated to identify problems that required corrective action. Findings are as follows: 1. The laboratory performed Toxicology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/18/19 at 8:25 a.m. 2. The laboratory performed proficiency testing (PT) using the College of American Pathologists (CAP) PT provider. 3. The laboratory received unacceptable PT results from CAP for the following PT surveys / events / samples / analytes. See below Survey: Urine Drug Screen Event: 2018 - C Sample: UDS-12 Analyte(s): Barbituate Survey: Urine Drug Confirmation Event: 2018 - C Sample: UDC-27 Analyte(s): Specific Gravity Sample: UDC-30 Analyte(s): Benzoyllecgonine 150 Delta-9-THC-COOH Sample: UDC-26 Analyte(s): Norbuprenorphine Survey: Urine Drug Confirmation Event: 2018 - D Sample(s):UDC-31, UDC-37 Analyte(s): Morphine, Total Sample: UDC-31 Analyte (s): 6-acetylmorphine Sample: UDC-32 Analyte(s): Phencyclidine Sample: UDC-36 Analyte(s): Specific Gravity Sample: UDC-39 Analyte(s): Benzoyllecgonine 150 Sample: UDC-37 Analyte(s): Hydrocodeine Sample: UDC-25 Analyte(s): Secobarbital Survey: Urine Drug Confirmation Event: 2019 - B Sample: UDC-14 Analyte(s): Methylenedioxymethamphetamine Sample: UDC-20 Analyte(s): Benzoyllecgonine 150 Sample: UDC-19 Analyte(s): Norbuprenorphine Sample: UDC-15 Analyte(s): Phenobarbital Survey: Urine Drug Confirmation Event: 2019 - C Sample: UDC-29 Analyte(s): Delta-9-THC-COOH 4. An evaluation of the cause of the unacceptable PT results and associated corrective action was not found during review of laboratory records. The laboratory was unable to provide evaluations or corrective actions upon request. 5. In an interview on 10/18/19 at 12:30 p.m., the GS confirmed the above finding. .

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

. Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure that Chemistry, Endocrinology and Hematology procedures (performance verification) were approved, signed, and dated by the laboratory director prior to use. Findings are as follows: 1. The laboratory performed Chemistry, Endocrinology and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/18/19 at 8:25 a.m. 2. The following analytical instrumentation were observed as present and available for use during the tour of the laboratory. - Beckman Coulter AU480 chemistry analyzer Date patient testing started: 2/19/18 Date performance verification review and approved by laboratory director (LD): 3/15/18 - Ortho VITROS ECi immunodiagnostic chemistry analyzer Date patient testing started: 2/19/18 Date performance verification review and approved by LD: Not found - Sysmex XN-550 hematology analyzer Date patient testing started: 8

/26/19 Date performance verification review and approved by LD: 9/6/19 3. Performance verification activities for each analyzer were acceptable and the laboratory began patient specimen testing in as indicated in laboratory records and as verified by email (10/25/19) by the GS. 4. The LD did not approve, sign, or date the performance verification documents prior to use of each analyzer. 5. In an interview on 10/18/19 at 3:30 p.m., the GS confirmed the above finding. .

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 demonstrate three of three new analyzers could obtain all performance characteristics comparable to those established by the manufacturer prior to testing patient specimens. Findings are as follows: 1. The laboratory performed Chemistry, Endocrinology and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/18/19 at 8:25 a.m. 2. The following analytical instrumentation were observed as present and available for use during the tour of the laboratory. - Beckman Coulter AU480 chemistry analyzer Start of patient testing: 2/19/18 - Ortho VITROS Eci immunodiagnostic chemistry analyzer Start of patient testing: 2/19/18 - Sysmex XN-550 hematology analyzer Start of patient testing: 8/26/19 3. Documents found in the Validation Study manuals for each system indicated reportable precision and reportable range performance verification activities were completed and approved by the Laboratory Director (LD) as follows: - Beckman Coulter AU480 chemistry analyzer Studies performed: 10/10/17 to 10/16/17 Results approved: 3/15/18 (See D5407) - Ortho VITROS Eci immunodiagnostic chemistry analyzer Studies performed: 09/29/17 to 10/04/17 Results approved: Not found (See D5407) - Sysmex XN-550 hematology analyzer Studies performed: 05/01/19 Results approved: 09/06/19 (See D5407) 4. Accuracy and expected range verification documents were not found in the Validation Study manuals for each system The laboratory was unable to provide accuracy and expected range verification documents upon request. 5. In an interview on 10/18/19 at 2:30 p.m., the GS confirmed the above finding.

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 observation, document review and interview with laboratory personnel, the

laboratory failed to ensure reference intervals were consistent between Chemistry, Hematology and Urinalysis procedures, and patient test reports. Findings are as follows: A. Chemistry: 1. The laboratory performed General Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/18/19 at 8:25 a.m. 2. A Beckman Coulter AU480 chemistry analyzer was observed as present and available for use during the tour. The laboratory began testing patient specimens using this analyzer on 2/19/2018 for general chemistry testing as indicated in laboratory records. 3. Reference intervals included in the Beckman Coulter AU480 Instructions For Use (IFU) manual for 14 of 14 analytes reviewed on date of survey were not consistent with those included on the patient test reports reviewed as indicated below. Date of Testing: 6/13/2018, Male - 40 years old Date of Testing: 6/25/2019, Female - 65 years old Analyte IFU Report Albumin 4.2-5.5 3.8-5.0 ALK* 34-104 30-106 ALT* 7-52 0-48 AST* 13-39 0-42 TBIL* 0.3-1.0 0.0-1.2 BUN* 7-25 5-21 Calcium 8.6-10.3 8.7-10.1 Chloride 98-107 100-106 CO2* 21-31 24-32 Creatinine 0.7-1.3 (M) 0.74-1.20 (F) 0.55-0.95 Glucose 74-109 65-100 Potassium 3.5-5.1 3.3-5.0 Total Protein 6.4-8.9 6.0-7.9 Sodium 136-145 136-142 4. In an interview at 4:45 p.m. on 10/18/19, the GS confirmed the above finding. *Note ALK Alkaline Phosphatase ALT Alanine Aminotransferase AST Aspartate Aminotransferase TBIL Total Bilirubin BUN Blood Urea Nitrogen CO2 Bicarbonate B. Hematology: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/18/19 at 8:25 a.m. 2. A Sysmex XN-550 hematology analyzer was observed as present and available for use during the tour. The laboratory began testing patient specimens using this analyzer on 8/26/2019 for general chemistry testing as indicated in laboratory records. 3. Reference intervals included in the Sysmex XN-550 Instructions For Use (IFU) manual for 13 of 13 analytes reviewed on date of survey were not consistent with those included on the patient test reports reviewed as indicated below. Analyte IFU Report WBC* (M) 4.23-9.07 4.0-11.0 (F) 3.98-10.04 RBC* (M) 4.63-6.08 (M) 4.4-5.8 (F) 3.93-5.22 (F) 3.8-5.3 HGB* (M) 13.7-17.5 (M) 13.5-17.5 (F) 11.2-15.7 (F) 11.5-15.8 HCT* (M) 40.1-51.0 (M) 40-50 (F) 34.1-4.9 (F) 35-45 MCV* (M) 79.0-92.2 80-98 (F) 79.4-94.8 MCH* (M) 25.7-32.2 25.5-34.0 (F) 25.6-32.2 MCHC* (M) 32.3-36.5 31.5-36.5 (F) 32.2-35.5 Platelet (M) 163-337 140-400 (F) 182-369 Basophils** (M) 0.01-0.08 0.0-0.2 (F) 0.01-0.08 Eosinophil** (M) 0.04-0.54 0.0-0.7 (F) 0.04-0.36 Monocytes** (M) 0.30-0.82 0.0-1.0 (F) 0.24-0.36 Lymphocytes** (M) 1.32-3.57 0.8-4.1 (F) 1.18-3.74 Neutrophils** (M) 1.78-5.38 1.8-8.0 (F) 15.6-6.13 4. In an interview at 3:45 p.m. on 10/18/19, the GS stated that the Hematology reference intervals had been adopted from another healthcare institution, but had not confirmed as part of the performance verification for the Hematology analyzer. (See D 5421) 5. In an interview at 4:45 p.m. on 10/18/19, the GS confirmed the above finding. *Note WBC White Blood Cell Count RBC Red Blood Cell Count HGB Hemoglobin HCT Hematocrit MCV Mean Corpuscular Volume MCH Mean Corpuscular Hemoglobin MCHC Mean Corpuscular Hemoglobin Concentration **Note WBC differential expressed as absolute counts B. Urinalysis: 1. The laboratory performed Urinalysis testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/18/19 at 8:25 a.m. 2. A Siemens Advantus analyzer and an Olympus BX-41 microscope were observed as present and available for use during the tour. 3. Reference intervals were not included in the Clinitek Adventus Urinalysis Analyzer procedure found in the laboratories policy and procedure manual. 4. In an interview at 4:45 p.m. on 10/18/19, the GS confirmed the above finding.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the technical consultant failed to evaluate the competency of 3 of 6 testing personnel in 2018. Findings are as follows: 1. The laboratory performed Chemistry, Toxicology, Endocrinology, Urinalysis, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/18/19 at 8:25 a.m 2. A competency assessment procedure was not found during review of laboratory policies and procedures. The laboratory was unable to provide a competency assessment procedure upon request. 3. A 2018 competency assessment for Testing Personnel 1 and 2 (TP1 and TP2) for Liquid Chromatography Mass Spectroscopy / Urine Drug Confirmation was not found during review of the laboratory's records. The laboratory was unable to provide the document upon request. 4. A 2018 competency assessment for Testing Personnel 6 (TP6) for Urine Drug Screens, General Chemistry, Endocrinology and Urinalysis (Macroscopic and Microscopic) was not found during review of the laboratory's records. The laboratory was unable to provide the document upon request. 5. In an interview on 10/18/19 at 10:45 a.m., the GS confirmed the above finding. .