Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2131019	09/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Axis Clinicals Llc	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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to verify the accuracy of one non-regulated analyte at least twice annually in 2020. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 8: 05 a.m. on 09/23/21. 2. An Ortho Vitros ECi chemistry analyzer was observed as present and available for use during the tour. 3. The laboratory performed Follicle Stimulating Hormone (FSH) testing on this analyzer beginning on 04/12/19 as indicated on the test listing provided by the laboratory. 4. Enrollment in Proficiency Testing (PT) for each analyte tested by the laboratory was required as established in the Proficiency Testing procedure found in the Toxicology and Clinical Laboratory SOP Binder. The laboratory utilized the College of American Pathologists (CAP) and the American Proficiency Institute (API) as the PT providers in 2019 and utilized CAP as the PT provider in 2020. 5. Verification of accuracy documents for FSH were not found during review of CAP and API PT records from 2019 and 2020. The laboratory was unable to provide FSH verification records upon request. 6. FSH testing was performed on zero patient specimens in 2019 and 71 patient specimens in 2020 as indicated on a laboratory report provided by TP1 on 09/23/21 that included all FSH testing from 04/12/19 - 09/23/21. 7. In an interview at 2:45 p.m. on 09/23/21, TP1 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 verify the reportable range for 2 of 3 new analytes implemented by the laboratory in 2021. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1)) during a tour of the laboratory at 8:05 a.m. on 09/23/21. 2. A Sysmex CA-620 coagulation analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification (PV) activities for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT) tested on the CA-620 analyzer were completed in August 2021. The laboratory began testing patient specimens using this analyzer on 08/24/21 as indicated by laboratory records. 4. Reportable range verification was required for new analytes as established in the Calibration Procedure located in the Toxicology and Clinical Laboratory SOP Binder 5. The reportable range verification for PT and aPTT was not found during review of PV records. The laboratory was unable to provide the missing documentation upon request. 6. In an interview at 2:05 p.m. on 09/2/21, TP1 confirmed the above finding. 7. Testing was performed on 34 PT patient specimens and 37 aPTT patient specimens since date of implementation through date of survey, 08/24/21- 09/23/21, as indicated on a laboratory report provided by TP1 on 09/30/21. .
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 ensure an annual competency assessment was performed for 1 testing personnel in 2020. Findings are as follows: 1. The laboratory performed Immunology, Chemistry, and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 8:05 a.m. on 09/23/21. 2. The Competency Assessment and Training procedure located in the Toxicology and Clinical Laboratory SOP Binder indicated personnel were evaluated for competency annually. 3. The 2020 annual competency assessment for TP1 was not found during review of personnel records. 4. The laboratory was unable to provide the missing annual competency assessment upon request. 5. In an interview at 10:00 a.m. on 09/23/21, TP1 confirmed the above finding. *This deficiency was previously cited during the 10/18/19 survey.*