Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0944557	12/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Healthcare Associates Of Texas - Mckinney 2760	1620 N Hardin Blvd Suite 2000, Lab 2, Mckinney, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: I. Based on a review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, review of the laboratory's Quality Assurance records, and staff interview, the laboratory failed to follow its own policy for monitoring, identifying, and correcting problems in general laboratory systems for unacceptable samples or testing event scores for 2017 Hematology /Coagulation (Event 1, 2, and 3) and 2018 Hematology/Coagulation (Events 1 and 2). The findings included: 1. Review of the laboratory's policy titled, "Proficiency

Testing" (signed by laboratory director 12/23/2016), stated the following: "If PT results for analytes are found to be unacceptable, the following steps should be taken: 1. Check your original documentation for discrepancies, including transcription, transposition, method coding, or PT program errors. 2. Check testing records for technical processing errors, including misidentification of specimen, misinterpretation of results, results mistakenly reported outside the reportable range, or when quality control was unacceptable. 3. Document the causes and the corrective action taken to prevent these events from happening in the future. 4. If the reasons for the errors are still not apparent, evaluate the test systems affected, including the instruments themselves, problems with calibration and linearity, and problems with specimen integrity and reconstitution. 5. Evaluate the test applications prior to the time of testing to include maintenance, controls, temperature and stability of reagents. 6. If possible, retest the proficiency testing samples, which may have been frozen if applicable. If the specimen results are now found to be acceptable: a. If one test or specimen as affected, it was most probably a 'random' analytical error, due to aliquot evaporation, pipetting or dilution error, or instrument instability or power surge. b. If two or more erroneous results were previously reported and biased in the same direction, it is referred to as a 'short-term systematic analytical error' due to improper instrument maintenance, reagent, deterioration or improper calibration. The Laboratory Staff and Director should review all PT scores and corrective action documentation, and sign and date them. Corrective action should be documented on the PT score sheet as well as the Quality Assessment Log for comprehensive review." 2. Review of the laboratory's API proficiency testing records from 2017 Hematology /Coagulation (events 1, 2, and 3), 2018 Hematology/Coagulation (events 1 and 2) revealed the following unacceptable scores: a. 2017 Event 1 Erthrocyte Count 80%; Unacceptable Sample HEM-03 Hematocrit 80%; Unacceptable Sample HEM-03 Hemoglobin 80%; Unacceptable Sample HEM-03 Leukocyte Count 80%; Unacceptable Sample HEM-03 Platelet Count 80%; Unacceptable Sample HEM-03 b. 2017 Event 2 Leukocyte Count 80%; Unacceptable Sample HEM-06 c. 2017 Event 3 Erthrocyte Count 80%; Unacceptable Sample HEM-14 Hematocrit 80%; Unacceptable Sample HEM-014 Hemoglobin 80%; Unacceptable Sample HEM-14 Leukocyte Count 80%; Unacceptable Sample HEM-14 d. 2018 Event 1 Erthrocyte Count 80%; Unacceptable Sample HEM-01 Hematocrit 80%; Unacceptable Sample HEM-01 Hemoglobin 80%; Unacceptable Sample HEM-01 3. Review of the "Performance Review and Corrective Action" page of the API performance evaluation revealed the following: a. 2017 Event 1 Reviewed by the (Lab Director or designee): Signed by the laboratory director on 05/01/2017 Corrective action taken (if indicated): No Corrective Action documented b. 2017 Event 2 Reviewed by the (Lab Director or designee): Signed by the laboratory director on 09/05/2017 Corrective action taken (if indicated): "No corrective action taken" c. 2017 Event 3 Reviewed by the (Lab Director or designee): Signed by the laboratory director on 01/16/2018 Corrective action taken (if indicated): "None taken, not needed, had passing results." a. 2018 Event 1 Reviewed by the (Lab Director or designee): Signed by the laboratory director on 06/01/2018 Corrective action taken (if indicated): "No corrective action needed. The analytes that scored less than 100% were ran by one MA" 4. The laboratory was asked to provide documentation of corrective actions for unacceptable samples for 2017 Hematology/Coagulation (Event 1, 2, and 3) and 2018 Hematology /Coagulation (Event 1). No documentation was provided. 5. An interview with testing person #1 on 12/04/2018 at 0947 hours in Exam room #5 confirmed the above findings. She stated that no corrected action was taken because the laboratory had a passing overall result of 80%. Word Key: MA-Medical Assistant II. Based on review of the laboratory's American Proficiency Institute's Microscopy proficiency testing records from 2017 (Events 1,2 and 3) and 2018 (Events 1, 2, and 3) and staff

	interview, it was revealed the laboratory failed to follow its own policy for monitoring, identifying, and correcting problems in general laboratory systems for unacceptable samples or testing event scores for the urine sediment sample for 2017 Event 1. The findings included: 1. Review of the laboratory's policy titled, "Proficiency Testing" (signed by laboratory director 12/23/2016), stated the following: "If PT results for analytes are found to be unacceptable, the following steps should be taken: 1. Check your original documentation for discrepancies, including transcription, transposition, method coding, or PT program errors. 2. Check testing records for technical processing errors, including misidentification of specimen, misinterpretation of results, results mistakenly reported outside the reportable range, or when quality control was unacceptable. 3. Document the causes and the corrective action taken to prevent these events from happening in the future. 4. If the reasons for the errors are still not apparent, evaluate the test systems affected, including the instruments themselves, problems with calibration and linearity, and problems with specimen integrity and reconstitution. 5. Evaluate the test applications prior to the time of testing to include maintenance, controls, temperature and stability of reagents. 6. If possible, retest the proficiency testing samples, which may have been frozen if applicable. If the specimen results are now found to be acceptable: a. If one test or specimen as affected, it was most probably a 'random' analytical error, due to aliquot evaporation, pipetting or dilution error, or instrument instability or power surge. b. If two or more erroneous results were previously reported and biased in the same direction, it is referred to as a 'short-term systematic analytical error' due to improper instrument maintenance, reagent, deterioration or improper calibration. The Laboratory Staff and Director should review all PT scores and corrective action documentation, and sign and date them. Corrective action should be documented on the PT score sheet as well as the Quality Assessment Log for comprehensive review." 2. A review of the laboratory's American Proficiency Institute's Microscopy proficiency testing records from 2017 (events 1,2 and 3) and 2018 (events 1, 2, and 3) revealed the laboratory failed to attain a satisfactory score of at least 80% for the urine sediment samples for 2017 Event 1: 2017 Event 1 Microscopy Urine Sediment Score 50% 3. Review of the "Performance Review and Corrective Action" page of the API performance evaluation revealed the following: 2017 Event 1 Reviewed by the (Lab Director or designee): Signed by the laboratory director on 05/01/2017 Corrective action taken (if indicated): No Corrective Action documented 4. The laboratory was asked to provide documentation of performing corrective actions for the unsatisfactory score. No documentation was provided. 5. An interview with testing person #1 on 12/04/2018 at 0947 hours in Exam room #5 confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies, and confirmed in an interview, the laboratory failed to follow manufacturer's instructions for Clay Adams Sedi-Stain recommended specimen type. The findings included: 1. The manufacturer's instructions for Clay Adams Sedi-Stain Concentration Stain (Catalog

	No. 420597) under the section titled "Summary of the Test" stated, "Sedi-Stain Concentrated Stain is a stabilized modification of the Sternheimer-Malbin urinary stain. This highly selective formula stains blood cells, casts and other formed elements in urinary sediment in a distinctive fashion which permits rapid and accurate identification." 2. Review of the laboratory policy titled "KOH and Wet Prep Instructions" stated the following: "Type of specimen: Vaginal Secretions: Test Procedure Information: ... .3. One drop of sedi-stain is added to the specimen and stirred with swabs." 3. The laboratory was asked to provide documentation that use of sedi-stain for a vaginal secretion specimen was acceptable. No documentation was provided. The laboratory failed to follow manufacturer's instructions for the recommended specimen type. 4. The above findings were confirmed during an interview with testing person #1 on 12/04/2018 at 1005 hours in Exam room #5.
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 review of the laboratory's submitted CMS Form 209, review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to perform annual competency assessment for 1 of 4 testing persons in 2017. The findings included: 1. A review of the laboratory's submitted CMS Form 209 revealed the following 4 testing persons requiring annual competency assessment in 2017: Testing person #1 Testing person #2 Testing person #3 Testing person #4 2. A review of the laboratory's personnel records revealed the following competency assessments were performed on testing person #4 (Date of Hire: 08/11/2016): Testing person #4 Training Checklist: 09/21/2016 2nd Competency Training Assessment: 12 /21/2016 Personnel Assessment: 02/27/2018 3. The laboratory was asked to provide documentation of the technical consultant performing a competency assessment on testing person #4 in 2017. No documentation was provided. 4. The above findings were confirmed in an interview with the laboratory representative on 12/04/2018 at 0920 hours in Exam Room 5.