Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2080140	08/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
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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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
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 review of the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for Fern testing and Breast wet smears in 2017 and 2018. The findings were: 1. A review of the laboratory's test menu revealed the laboratory performed Fern testing and Breast wet smears in 2017 and 2018. 2. A review of the laboratory's records from 2017 and 2018 revealed the laboratory failed to have documentation of performing the following twice annual accuracy assessments: a) 2017 - 1 Fern test - 1 Breast wet smear b) 2018 - 2 Breast wet smears 3. The laboratory was asked to provide documentation of performing the identified accuracy assessments. No documentation was provided. 4. An interview

	with the technical consultant on 08/01/2019 at 1527 hours in the conference room - after her review of the records- confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's procedure manual, and staff interview, it was revealed the laboratory failed to have documentation of procedures for Fern testing and Breast wet smear testing. The findings were: 1. A review of the laboratory's test menu revealed the laboratory performed Fern testing and Breast wet smear testing in 2017 and 2018. 2. A review of the laboratory's procedure manual revealed the laboratory failed to had documentation of procedures for each of the identified tests. 3. The laboratory was asked to provide documentation of procedures for Fern testing and Breast wet smear testing. No documentation was provided. 4. The laboratory performed 18 Fern tests and 2 Breast wet smear tests in 2018. 5. An interview with the technical consultant on 08/01/2019 at 1525 hours in the conference area revealed the laboratory did not have procedures for Fern testing and Breast wet smear testing. This confirmed the 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 the manufacturer's instructions for the BD Affirm III Microbial Identification Test, review of the laboratory's test records, and staff interview, it was revealed the laboratory failed to ensure samples were tested within 4 hours of sample preparation. The findings were: 1. A review of the manufacturer's instructions for the BD Affirm III Microbial Identification Test (670160JAA, 2010/08) under the section titled "Specimen Storage and Transportation" revealed: "The total time between placing the swab into the sample collection tube land proceeding with the sample preparation should be no longer than 1 h (hour) if the sample is stored at room temperature, or 4 h (hour) if the sample is stored at 2 to 8C." 2. A review of the laboratory's test record from September 2017 to June 2019 revealed the laboratory stored all samples at 2 to 8C after collection, so the laboratory had up to 4 hours to perform sample preparation. Further review of the records revealed the following samples where the time from collection to preparation exceeded 4 hours. a) September 26, 2017 specimen id: 2/13/70 collection time: 03:39 preparation time: 08:14 time: 4 hours 35 minutes b) October 9, 2017 specimen id: 10/9/95 collection time: 12:30 preparation time: 4:46 time: 4 hours 16 minutes c) October 9, 2017 specimen id: 12/15 /87 collection time: 12:34 preparation time: 4:56 time: 4 hours 12 minutes d) February

	5, 2018 specimen id: 10/16/93 collection time: 8:41 preparation time: 12:50 time: 4 hours 9 minutes e) October 30, 2018 specimen id: 9/19/85 collection time: 12:04 preparation time: 4:05 time: 4 hours 1 minute f) June 3, 2019 specimen id: 4/7/85 collection time: 8:40 preparation time: 1:05 time: 4 hours 25 minutes 3. An interview with the technical consultant on 08/01/2019 at 1515 hours in the conference area - after her review of the records- confirmed the findings.
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 Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory laboratory failed to have documentation of the technical consultant performing annual competency assessments in 2017 and 2018 for 1 of 6 testing personnel. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 6 testing personnel who performed moderately complex testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of competency assessments being performed in 2017 and 2018 for testing personnel number 5. 3. The laboratory was asked to provide documentation of competency assessments in 2017 and 2018 for testing personnel number 5. No documentation was provided. 4. An interview with the technical consultant on 08/01 /2019 at 1424 hours in the conference area revealed she had not performed competency assessments on testing personnel number 5 in 2017 and 2018. This confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory laboratory failed to have documentation of education to qualify 1 of 6 testing personnel to performed moderate complexity testing (refer to 6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a

	chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory laboratory failed to have documentation of education to qualify 1 of 6 testing personnel to performed moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 6 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for testing personnel number 5. 3. The laboratory was asked to provide documentation of education for testing personnel number 5. No documentation was provided. 4. An interview with the technical consultant on 08/01/2019 at 1424 hours in the conference area revealed the laboratory did not have education records for testing personnel number 5. This confirmed the findings.