Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0672012	11/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Co Dept Of Health & Human Services	2377 N Stemmons Freeway Suite 003, Dallas, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory 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.
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: I. Based on review of manufacturer's instructions, direct observation, patient records, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for ensuring the correct procedure for the ELVIS HSV ID Test System. Findings included: 1. Review of manufacturer's instructions for the ELVIS HSV ID Test System stated the following: "PROCEDURE ... Specimen Inoculation and Incubation ... 7. After all inoculations have been completed, reseal the plate with a disposable

tray seal and replace the cover on the plate, or recap the shell vials, and centrifuge at 700xg for 60 minutes at ambient temperature ... Cell Fixation and Staining 1. Aspirate the medium completely from each monolayer and add 0.25 mL of Solution 1 (Cell Fixative) to each monolayer. 2. Mix by rocking to ensure that each monolayer is uniformly covered with solution. 3. Allow to stand for a minimum of 1 minute and a maximum of 10 minutes. 4. Aspirate Solution 1 from each monolayer. 5. Add 0.25 mL Solution 2 (Staining Buffer) to each monolayer. 6. Mix by rocking to ensure that each monolayer is uniformly covered with solution. 7. Cover containers and place at 35C-37C for 1 to 5 hours. 8. Upon completion of step VI, above, remove coverslips from shell vials (if required) for interpretation as follows: a. Lift the coverslip carefully from the bottom of the shell vial using a bent teasing needle. b. Remove the coverslip with forceps. Take care to identify the cell monolayer side of the coverslip. c. Wash the coverslip gently by several immersions in a beaker of distilled water while still holding it with the forceps. d. Blot excess water by touching the edge of the coverslip to absorbent paper ... 9. Examine each monolayer entirely for stained cells using a light microscope with a magnification of 100X ..." 2. On 11/03/2020 at 11:30 am, testing person 7 (TP-7) was observed performing the specimen inoculation and incubation procedure. The following was the procedure performed by the testing person after all inoculations were completed: TP-7 recapped the shell vials and centrifuged them at 1850 RPM (804xg) for 60 minutes at ambient temperature. The laboratory failed to follow manufacturer's instructions for centrifugation at 700xg for the HSV test procedure. On 11/04/2020 at 10:55 am, TP-7 was observed performing the cell fixation and staining procedure. The following was the procedure performed by the testing person: 1. Aspirated the medium from each monolayer and added 0.25 mL of Solution 1 to each monolayer. 2. Allowed to stand for approximately 2 minutes. 3. Aspirated Solution 1 from each monolayer. 4. Added 0.25 mL Solution 2 to each monolayer. 5. Covered containers and place at 35C-37C for approximately 2 hours. The laboratory failed to follow manufacturer's instructions to mix by rocking to ensure that each monolayer is uniformly covered with solution for the HSV tests procedure. On 11/04/2020 at 1:30 pm, TP-7 continued performing the rest of the procedure as follows: 1. Removed coverslips from shell vials as follows: a. Lifted the coverslip from the bottom of the shell vial using a bent teasing needle. b. Removed the coverslip with forceps. 2. Examined each monolayer using a light microscope with a magnification of 100X. The laboratory failed to follow manufacturer's instructions for performing HSV tests. 3. The laboratory failed to follow manufacturer's instructions for HSV test procedures for the following patients from the above-mentioned observations: Patient Barcode # 20015633, 20015856, 200115948, 20015949 4. During an interview on 11/04/2020 at 2:15 pm, TP-7 and Quality Control Analyst confirmed the laboratory failed to follow manufacturer's instructions for performing HSV test procedures. 43232 II. Based on review of manufacturer's instructions, laboratory's policy, quality control records, patient records, and interview with staff, the serology laboratory failed to follow ASI Rapid Card Test for Syphilis manufacturer's instructions for documenting the correct interpretation of qualitative quality control (QC) for 15 of 15 days in 09/2020 and 10/2020. Findings included: 1. Review of ASI Rapid Card Test for Syphilis manufacturer's instructions (package insert) stated, "VISUAL INTERPRETATION OF RESULTS - QUALITATIVE: 2. Results for the ASI RPR Card Test should be reported only as reactive or nonreactive, regardless of the degree of reactivity. Minimal to moderate reactivity should always be reported as reactive." 2. Review of the laboratory's "ASI Rapid Plasma Reagin" policy stated, "13. INTERPRETATION OF THE RESULTS: QUALITATIVE: RESULT: Reactive (R), Moderately Reactive, Minimally Reactive; INTERPRETATIONS: Reactive (R) implies non-treponemal antibodies detected." 3. Review of the serology laboratory's ASI RPR quality control worksheets from 09

	/2020 and 10/2020 revealed the following documented qualitative control results were not consistent with manufacturer's interpretation of qualitative results (reactive): External QC Lot # 9B25RC, expiration date 10/31/2020 - 9/14/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 9/15/2020 -"Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 9/16/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 9/17/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 9/18/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 9/29/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 9/30/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 10/5/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 10/6/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 10/7 /2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 10/19/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 10/20/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 10/21/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 10/22/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 10/23/2020 - "Control (++): QUAL Result: ++; Control (+): QUAL Result: +" 4. Review of a random sampling of patient records from 9/2020 and 10/2020 revealed the following documented RPR qualitative results: Patient 15335 - date reported 9/17/2020; RPR result: Reactive Patient 17225 - date reported 10/29/2020; RPR result: Reactive Patient 17220 - date reported 10/29/2020; RPR result: Reactive Patient 17222 - date reported 10/29/2020; RPR result: Reactive The laboratory's qualitative QC results were not consistent with patient qualitative results, as required. 5. During an interview on 11/3/2020 at 2:45 pm, the QC-QA Coordinator reviewed the above QC worksheets and confirmed qualitative results should be documented as "R" (reactive) instead of ++ or +.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, temperature logs, and confirmed in interview, the laboratory failed to define a temperature range for the NAPCO Series 8000DH CO2 Incubator, in which herpes simplex virus (HSV) patient specimens were incubated, to ensure temperature did not exceed manufacturer instructions for 11 of 11 months in 2020. Findings included: 1. Review of the ELVIS HSV ID Test System instructions page 4 stated "MATERIALS REQUIRED BUT NOT PROVIDED ... Incubator to maintain 35C to 37C ..." 2. Review of temperature charts from 01/2020-11/2020 revealed the laboratory defined a temperature range for the incubator as 34.0 C to 36.0 C. The laboratory failed to define a temperature range to ensure temperatures did not exceed manufacturer's instructions for HSV patient specimens during incubation. 3. During an interview on 11/03/2020 at 2:00 pm, the Quality Coordinator confirmed the above findings.

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to document negative and positive control material for qualitative herpes simplex virus (HSV) cultures for 4 of 28 days in 2019 (random review April through June) and 7 of 24 days in 2020 (random review August through October). Findings included: 1. Review of the laboratory's HSV policy stated: "Quality Assurance An extensive Quality Assurance (QA) Program is mandatory to ensure quality results for Herpes simplex virus detection. The QA Program for our Herpes simplex virus detection will consist of the following ... C. A positive control (HSV-1) and a negative control (uninoculated shell vial) is tested each time patients are tested. If unacceptable, patients [sic] results are not reported." 2. Review of manufacturer's instructions for the ELVIS HSV ID Test System stated the following: "QUALITY CONTROL PROCEDURES Guidance on appropriate quality control procedures and practices may be found in the above reference to the CLSI (formerly NCCLS) C24-A, Approved Guideline "Statistical quality control for quantitative measurements: Principles and definitions, 1997", 7.2 (Control materials: Characteristics) and 8.2 (QC applications: Frequency of control measurements). To assure that the culture, cell fixation and stain development procedures have been properly conducted and to provide a basis for interpreting specimen results, an HSV-infected and an uninfected monolayer should be included with each run. If the controls do not perform as expected, review the steps and conditions under which the test was performed to determine the cause(s). Do not report results until controls perform properly." 3. Review of QC records and patient between 04/01-06/28/2019 and 08/07-10/30/2020 revealed laboratory failed to document negative and positive controls each day of patient testing on the following days: 04/16/2019; Patient IDs: 101 04/18/2019; Patient IDs: 102, 103, 104, 105, 106, 107, 108, 109 05/02/2019; Patient IDs: 128 05/14 /2019; Patient IDs: 140 08/11/2020; Patient IDs: 176 08/21/2020; Patient IDs: 182, 183 09/04/2020; Patient IDs: 196 09/10/2020; Patient IDs: 197, 198, 199, 200, 201, 202 09/16/2020; Patient IDs: 204, 205, 206, 207 10/16/2020; Patient IDs: 227, 228, 229, 230, 231, 232, 233, 234, 235 10/30/2020; Patient IDs: 244, 245 4. During an interview on 11/03/2020 at 10:45 am; the Quality Manager confirmed the laboratory failed to perform negative and positive QC every day of patient testing.
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 review of Centers for Medicare and Medicaid (CMS) 209 form, personnel records (2019, 2020), and in interview with staff, the laboratory director failed to ensure performance competency was evaluated and documented for 2 of 2 testing persons at least semiannually during the first year that testing persons analyze patient specimens and failed to ensure competency assessment was maintained for 10 of 10 individuals who perform high complexity testing in 2019. Findings included: 1. Review of the submitted CMS 209 form revealed the following 2 Testing Persons (TP) listed to perform high complexity testing: a. Testing Person #9; Date of Hire 09 /10/2018 b. Testing Person #14; Date of Hire 03/04/2019 2. Review of personnel records for 01/01/2018 through 11/04/2020 revealed no documentation of semiannual competency assessment during the first year that TP#9 and TP#14 performed patient testing. 3. Review of the submitted CMS 209 form revealed the following 10 testing persons (TP) listed to perform high complexity testing in 2019. a. Testing Person #1; Date of Hire 01/18/2005 b. Testing Person #2; Date of Hire 02/22/2016 c. Testing Person #4; Date of Hire 04/12/2004 d. Testing Person #6; Date of Hire 12/27/2016 e. Testing Person #7; Date of Hire 09/30/2002 f. Testing Person #8; Date of Hire 03/20 /2017 g. Testing Person #10; Date of Hire 02/16/2015 h. Testing Person #11; Date of Hire 09/29/2014 i. Testing Person #12; Date of Hire 06/18/2017 j. Testing Person #13; Date of Hire 03/21/2016 4. Review of personnel records for 2019 revealed no documentation of competency evaluation for TP#1, TP#2, TP#4, TP#6, TP#7, TP#8, TP#10, TP#11, TP#12, and TP#13. The Laboratory director failed to ensure that competency assessments had been performed and documented for testing persons to include: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. f) Assessment of problem solving skills. 3. In an interview on 11/03/2020 at 11:59 AM, Technical Supervisor #2 was asked to provide documentation of semi-annual competency evaluation for TP#9 and TP#14 and documentation of competency evaluation for 2019. No documentation was provided. The technical supervisor #2 stated that the laboratory did not perform any competency evaluations for 2019. This confirmed the above findings.