Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0672012	06/09/2022
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 NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1240 Pre-Analytic Systems 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 Southern Operations Branch-Dallas 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.
D2026	BACTERIOLOGY CFR(s): 493.823(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) report 155 individual laboratory profile, College of American Pathologist (CAP) proficiency testing records, laboratory documents, and confirmed in an interview, the laboratory failed to include patient remedial actions for 1 of 3 failed

	gram stain proficiency testing events reviewed in 2021. The findings include: 1. Review of the CASPER 155 report listed a failed score of 43%, a passing score being 80% or higher, for the 2021 Bacteriology Event 2. 2. Review of laboratory "Nonconforming Event Record" for the Bacteriology Event 2 failure in 2021, document code: DCHHS-L5Q-01, section "Root Cause" stated: "Technician Error: Over-decolorizing multiple PT slides simultaneously" 3. Surveyor queried the quality manager (QM), on 6/8/2022 at 13:45 hours, for documentation that part of the remedial action for the PT failure included patient assessment, and none was provided. 4. In an interview on 6/8/2022 at 13:47 hours, in the conference room, the QM confirmed that patient remedial action was not included in the laboratory's investigation into the proficiency testing failures for scores less than 80%.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, the laboratory's policy and procedure, laboratory records, observation, test requisitions/test reports, worklists, worksheets, LIS query, TAT query, receiving logs, and interview, it was revealed that the laboratory failed to meet the requirements for the preanalytical system, as evidenced by: 1. The laboratory failed to ensure the test requisition for Covid samples included the time of specimen collection for six out of six samples reviewed (refer to D5305). 2. The laboratory failed to ensure HIV-1 specimens were tested on the Panther System within five days of collection when stored at 2 to 8 degrees Celsius for 19 out of 415 specimens reviewed (refer to D5311 I). 3. The laboratory failed to ensure HIV-1 specimens tested on the Panther System were transferred to the SAT within 3 days of collection when stored at 2 to 8 degrees Celsius for up to five days after collection, or frozen for storage up to 90 days to allow for testing for 88 out of 415 specimens (refer to D5311 II). 4. The laboratory failed to ensure Covid samples tested on the Panther System were processed and lysed within 96 hours for three out of 982 samples reviewed (refer to D5311 III). 5. The laboratory failed to ensure the preanalytic storage requirements were met for three of three patient samples (sampling) received for Non-variola Orthopoxvirus and Orthopoxvirus testing (refer to D5311 IV). 6. The laboratory failed to ensure the temperature of patient's blood specimens used for serology testing were maintained during transport (refer to D5311 V). 7. The laboratory failed to define the acceptability criteria for "COLD" specimens in the Client Services Manual (refer to D5317). KEY: LIS = Laboratory Information System TAT = Turn Around Time HIV-1 = Human Immunodeficiency Type 1 SAT = Specimen Aliquot Tube
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting

	the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, observation, test requisitions, test reports, LIS query, and interview, the laboratory failed to ensure the test requisition for Covid samples included the time of specimen collection for six out of six samples reviewed. Findings follow. 1. Review of the Aptima SARS-CoV-2 Assay (Panther System) Standard Operating Procedure, version 1.5, May 2022, under Storage stated, "Specimens in VTM/UTM will be stored at 2 to 8 degrees Celsius for no more than 96 hours before being transferred into Hologic Specimen Lysis Tubes." 2. Surveyor observed on June 7, 2022 at 1100 hours, testing personnel #9 accessioning specimens into the Horizon LIMS using the High-speed Login where a field for "Turn Code" stated acceptability as "5 days from receipt". After obtaining a specimen Lab ID#, he transferred the sample from the Primary Specimen Container to the associated Hologic Specimen Lysis Tube. 3. Random review of patient test requisitions with the corresponding test reports showed six of six specimens did not include the time of collection: Lab ID# Date of collection Received/Accessioned in Lab 2201180008 01/14/2022 @ 00:00 01/18/2022 @ 10:34 2201180009 01/14/2022 @ 00:00 01/18/2022 @ 10:40 2201310001 01/28/2022 @ 00:00 01/31/2022 @ 13:40 2202020046 01/28/2022 @ 00:00 02/02/2022 @ 11:51 2202020060 01/31/2022 @ 00:00 02/02/2022 @ 12:48 2202020062 02/02/2022 @ 00:00 02/02/2022 @ 16:19 * Time of collection was not on the test requisitions or test reports and was entered as 00:00, midnight. 4. Interview with the Technical Supervisor #2, as listed on the CMS Form 209, on June 8 at 1200 hours confirmed the collection time was not entered onto the test requisition and agreed this was a time sensitive test with the transfer of the sample to the lysis tube. 5. Review of the LIS query for SARS-CoV-2 showed a semi-annual test volume of 982 from Dec 1, 2021 - May 31, 2022. Key: VTM Viral Transport Media
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, the laboratory's policy and

procedure, observation, interview, test requisitions/test reports, worklists, and worksheets, the laboratory failed to ensure HIV-1 specimens were tested on the Panther System within five days of collection when stored at 2 to 8 degrees Celsius for 19 out of 415 specimens reviewed. Findings follow. 1. Review of the manufacturer's instructions titled Hologic Aptima HIV-1 Quant Dx Assay, AW-11853-001, Rev 003, under Specimen Collection and Storage at A. Specimen Collection stated, "Plasma or Serum can be tested on the Panther system in the primary tube or transferred to the secondary Aptima Specimen Aliquot Tube (SAT) and can be tested on the Panther system. ... If not tested immediately, plasma and serum can be stored in accordance with the specifications below. If transferred to the SAT, plasma may be frozen at -20 degrees Celsius or -70 degrees Celsius, and serum may be frozen at -20 degrees Celsius. Do not exceed three freeze-thaw cycles to avoid affecting the result. Do not freeze specimens in EDTA, ACD, or serum primary collection tubes." Under Specimen Collection and Storage at Specimen Storage Conditions 4. SST Specimens stated "For up to 24 hours after specimen collection, SSTs containing centrifuged serum may be stored at 2 to 30 degrees Celsius. After 24 hours, serum may be stored for a longer period under one of the following conditions: In the SST at 2 to 8 degrees Celsius for up to 5 days. In the SST at 2 to 8 degrees for up to 5 days, or In the SAT or SST at -20 degrees Celsius for up to 7 days." 2. Review of the Aptima HIV-1 Quant Dx Assay Standard Operating Procedure, Version 1.0, May 2022, under 6. Specimen Requirements at 6.4 Storage/Incubation stated, "2) If stored at 2 to 8 degrees Celsius, centrifuged plasma or serum may be kept in the primary tube, PPTs, or SSTs for up to THREE DAYS. 3) Centrifuged plasma or serum transferred to a SAT can be stored at 2 to 8 degrees Celsius for up to FIVE DAYS. 4) Plasma or serum transferred into a SAT, may be stored at -20 to -70 degrees for up to 90 DAYS. Do not freeze specimen samples in primary collection tubes." 3. Surveyor observation on June 8, 2022 at 1100 hours with testing personnel #3, as listed on the CMS form 209, during the test run confirmed all the samples were in their primary collection tube, previously stored at 2 to 8 degrees. Surveyor pointed out there was a sample, Lab ID HIV 2302, older than 7 days on that test run. 4. Interview with Testing personnel #3 on June 8, 2022 at 1100 hours stated the sample had been received in the lab on June 6 and was in the lab for less than 3 days indicating she thought the sample was good. Test reports were later requested from that test run and specimen HIV 2302 had been rejected with the comment "the sample received is outside the stability window for HIV-1 RNA testing. Please resubmit sample within 3 days of collection if HIV-1 RNA testing is required." 5. Random review of 3 out of 6 test runs from May 31, 2022 - June 7, 2022 against the test requisition/test report (external clients), and worklists and worksheets (internal clients) showed 19 out of 415 specimens (83 pools*) were over 5 days old: a. Test run performed on May 31, 2022, 11 out of 185 specimens (37 pools) were older than 5 days: LAB ID# Collection Date/Time Date of Test Run Elapsed Time HIV IND85 5/25/2022 @ 2:20 PM 5/31/2022 @ 12:59 PM 5 days, 22 hours, 39 minutes HIV IND86 5/23/2022 @ 10:58 AM 5/31/2022 @ 12:59 PM 8 days, 2 hours, 1 minute HIV IND87 5/25/2022 @ 1:30 PM 5/31/2022 @ 12:59 PM 5 days, 23 hours, 29 minutes HIV 2170 5/26/2022 @ 10:45 AM 5/31/2022 @ 12:59 PM 5 days, 2 hours, 14 minutes HIV 2171 5/25/2022 @ 9:26 AM 5/31/2022 @ 12:59 PM 6 days, 3 hours, 33 minutes HIV 2172 5/25/2022 @ 10:06 AM 5/31/2022 @ 12:59 PM 6 days, 2 hours, 53 minutes HIV 2173 5/25/2022 @ 2:20 PM 5/31/2022 @ 12:59 PM 5 days, 22 hours, 39 minutes HIV 2175 5/26/2022 @ 10:24 AM 5/31/2022 @ 12:59 PM 5 days, 2 hours, 35 minutes HIV 2177 5/23/2022 @ 12:36 PM 5/31/2022 @ 12:59 PM 8 days, 23 minutes HIV 2178 5/26/2022 @ 8:40 AM 5/31/2022 @ 12:59 PM 5 days, 4 hours, 19 minutes HIV 2179 5/26/2022 @ 8:45 AM 5/31/2022 @ 12:59 PM 5 days, 4 hours, 14 minutes b. Test run performed on June 4, 2022, 1 out of 130 specimens (26 pools) were older than 5 days: LAB ID# Collection Date/Time Date of

Test Run Elapsed Time HIV 2241 5/27/2022 @ 13:40 6/04/2022 @ 4:29 PM 7 days, 14 hours, 49 minutes c. Test run performed on June 7, 2022, 7 out of 100 specimens (20 pools) were older than 5 days: LAB ID# Collection Date/Time Date of Test Run Elapsed Time HIV IND88 5/31/2022 @ 1:27 PM 6/07/2022 @ 12:39 PM 7 days, 11 hours, 12 minutes HIV IND89 6/02/2022 @ 10:10AM 6/07/2022 @ 12:39 PM 5 days, 2 hours, 29 minutes HIV IND91 5/31/2022 @ 8:40 AM 6/07/2022 @ 12:39 PM 7 days, 3 hours, 59 minutes HIV 2258 6/01/2022 @ 12:25 PM 6/07/2022 @ 12:39 PM 6 days, 0 hours, 14 minutes HIV 2259 6/01/2022 @ 12:00 PM 6/07/2022 @ 12:39 PM 6 days, 0 hours, 39 minutes HIV 2260 6/01/2022 @ 12:30 PM 6/07/2022 @ 12:39 PM 6 days, 0 hours, 9 minutes HIV 2261 6/01/2022 @ 6:00 PM 6/07/2022 @ 12:39 PM 5 days, 18 hours, 39 minutes None of the above test's requisitions/test reports/worklists /worksheets indicated any of the specimens had been poured over into the SAT, or frozen, or the number of freeze thaw cycles. They were stamped with "Specimen Temperature Arrived Cold" (see D5311 V and D5317). 6. Interview with Testing personnel #3 on June 8, 2022 at 0915 hours confirmed specimens tested for HIV-1 and HIV-2 Ag-Ab that were non-reactive were then reflexed to pooled HIV-1 Qualitative testing. Interview on June 9, 2022 at 1155 hours in the lab with testing personnel #3 confirmed all the tubes tested for the HIV-1 were received in the primary collection tube and transferred to a SAT for the pooled sample used in testing. 7. Surveyor observed on June 9, 2022 at 1155 hours all the racks from previous runs were stored in the refrigerator and contained samples stored in the primary collection tube. 8. Review of the test runs showed testing began May 31, 2022, and from May 31, 2022 to June 7, 2022 showed 610 specimens were tested. * The laboratory pooled 5 specimens per SAT for the test. KEY: SAT = Specimen Aliquot Tube PPT = Plasma Preparation Tube SST = Serum Separator Tube ACD = Acid Citrate Dextrose EDTA = Ethylenediaminetetraacetic acid HIV-1 = Human Immunodeficiency Type 1 II. Based on review of manufacturer's instructions, the laboratory's policy and procedure, observation, interview, test requisitions/test reports, worklists, and worksheets, the laboratory failed to ensure HIV-1 specimens tested on the Panther System were transferred to the SAT within 3 days of collection when stored at 2 to 8 degrees Celsius for up to five days after collection, or frozen for storage up to 90 days to allow for testing for 88 out of 415 specimens. Findings follow. 1. Review of the manufacturer's instructions titled Hologic Aptima HIV-1 Quant Dx Assay, AW-11853-001, Rev 003, under Specimen Collection and Storage at A. Specimen Collection stated, "Plasma or Serum can be tested on the Panther system in the primary tube or transferred to the secondary Aptima Specimen Aliquot Tube (SAT) and can be tested on the Panther system. ... If not tested immediately, plasma and serum can be stored in accordance with the specifications below. If transferred to the SAT, plasma may be frozen at -20 degrees Celsius or -70 degrees Celsius, and serum may be frozen at -20 degrees Celsius. Do not exceed three freeze-thaw cycles to avoid affecting the result. Do not freeze specimens in EDTA, ACD, or serum primary collection tubes." Under Specimen Collection and Storage at Specimen Storage Conditions 4. SST Specimens stated "For up to 24 hours after specimen collection, SSTs containing centrifuged serum may be stored at 2 to 30 degrees Celsius. After 24 hours, serum may be stored for a longer period under one of the following conditions: In the SST at 2 to 8 degrees Celsius for up to 5 days. In the SST at 2 to 8 degrees for up to 5 days, or In the SAT or SST at -20 degrees Celsius for up to 7 days." 2. Review of the Aptima HIV-1 Quant Dx Assay Standard Operating Procedure, Version 1.0, May 2022, under 6. Specimen Requirements at 6.4 Storage/Incubation stated, "2) If stored at 2 to 8 degrees Celsius, centrifuged plasma or serum may be kept in the primary tube, PPTs, or SSTs for up to THREE DAYS. 3) Centrifuged plasma or serum transferred to a SAT can be stored at 2 to 8 degrees Celsius for up to FIVE DAYS. 4) Plasma or serum transferred into a SAT, may be stored at -20 to -70 degrees for up to 90 DAYS.

Do not freeze specimen samples in primary collection tubes." 3. Surveyor observation on June 8, 2022 at 1100 hours with testing personnel #3, as listed on the CMS form 209, during the test run confirmed all the samples were in their primary collection tube, previously stored at 2 to 8 degrees. Surveyor pointed out there was a sample, Lab ID HIV 2302, older than 7 days on that test run. 4. Interview with Testing personnel #3 on June 8, 2022 at 1100 hours stated the sample had been received in the lab on June 6 and was in the lab for less than 3 days indicating she thought the sample was good. Test reports were later requested from that test run and specimen HIV 2302 had been rejected with the comment "the sample received is outside the stability window for HIV-1 RNA testing. Please resubmit sample within 3 days of collection if HIV-1 RNA testing is required." 5. Random review of 3 out of 6 test runs from May 31, 2022 - June 7, 2022 against the test requisition/test report (external clients), and worklists and worksheets (internal clients) showed 86 out of 415 specimens (83 pools*) were over 3 days old: a. Test run performed on May 31, 2022, 20 out of 185 specimens (37 pools) were older than 3 days: LAB ID# Collection Date/Time Date of Test Run Elapsed Time HIV IND85 5/25/2022 @ 2:20 PM 5/31/2022 @ 12:59 PM 5 days, 22 hours, 39 minutes HIV IND86 5/23/2022 @ 10:58 AM 5/31/2022 @ 12:59 PM 8 days, 2 hours, 1 minute HIV IND87 5/25/2022 @ 1:30 PM 5/31/2022 @ 12:59 PM 5 days, 23 hours, 29 minutes HIV 2170 5/26/2022 @ 10:45 AM 5/31/2022 @ 12:59 PM 5 days, 2 hours, 14 minutes HIV 2171 5/25/2022 @ 9:26 AM 5/31/2022 @ 12:59 PM 6 days, 3 hours, 33 minutes HIV 2172 5/25/2022 @ 10:06 AM 5/31/2022 @ 12:59 PM 6 days, 2 hours, 53 minutes HIV 2173 5/25/2022 @ 2:20 PM 5/31/2022 @ 12:59 PM 5 days, 22 hours, 39 minutes HIV 2174 5/26/2022 @ 11:35 AM 5/31/2022 @ 12:59 PM 5 days, 1 hours, 24 minutes HIV 2175 5/26/2022 @ 10:24 AM 5/31 /2022 @ 12:59 PM 5 days, 2 hours, 35 minutes HIV 2176 5/26/2022 @ 1:36 PM 5/31 /2022 @ 12:59 PM 4 days, 23 hours, 23 minutes HIV 2177 5/23/2022 @ 12:36 PM 5 /31/2022 @ 12:59 PM 8 days, 23 minutes HIV 2178 5/26/2022 @ 8:40 AM 5/31/2022 @ 12:59 PM 5 days, 4 hours, 19 minutes HIV 2179 5/26/2022 @ 8:45 AM 5/31/2022 @ 12:59 PM 5 days, 4 hours, 14 minutes HIV 2180 5/26/2022 @ 11:15 AM 5/31 /2022 @ 12:59 PM 5 days, 1 hours, 44 minutes HIV 2181 5/26/2022 @ 12:28 PM 5/31 /2022 @ 12:59 PM 5 days, 0 hours, 31 minutes HIV 2182 5/26/2022 @ 3:05 PM 5/31 /2022 @ 12:59 PM 4 days, 21 hours, 54 minutes HIV 2183 5/26/2022 @ 3:40 PM 5/31 /2022 @ 12:59 PM 4 days, 21 hours, 19 minutes HIV 2184 5/26/2022 @ 4:13 PM 5/31 /2022 @ 12:59 PM 4 days, 20 hours, 46 minutes HIV 2185 5/26/2022 @ 5:37 PM 5/31 /2022 @ 12:59 PM 4 days, 19 hours, 22 minutes HIV 2186 5/26/2022 @ 6:06 PM 5/31 /2022 @ 12:59 PM 4 days, 18 hours, 53 minutes b. Test run performed on June 4, 2022, 28 (external and internal) out of 130 specimens (26 pools) were older than 3 days: LAB ID# Collection Date/Time Date of Test Run Elapsed Time HIV 2240 6/01 /2022 @ 8:59 AM 6/04/2022 @ 4:29 PM 3 days, 7 hours, 30 minutes HIV 2241 5/27 /2022 @ 13:40 6/04/2022 @ 4:29 PM 7 days, 14 hours, 49 minutes HIV 2255 6/01 /2022 @ 8:26 AM 6/04/2022 @ 4:29 PM 3 days, 8 hours, 3 minutes HIV 2256 6/01 /2022 @ 9:07 AM 6/04/2022 @ 4:29 PM 3 days, 7 hours, 22 minutes HIV 2257 6/01 /2022 @ 1:21 PM 6/04/2022 @ 4:29 PM 3 days, 3 hours, 8 minutes Review of the internal client worklist for the test run performed on June 4, 2022 against the collection time/spin time worksheet showed the following internal clients in the same test run were older than 3 days: 20093130 6/01/2022 @ 12:45 PM 6/04/2022 @ 4:29 PM 3 days, 3 hours, 44 minutes 20093131 6/01/2022 @ 12:35 PM 6/04/2022 @ 4:29 PM 3 days, 3 hours, 54 minutes 20093132 6/01/2022 @ 11:40 AM 6/04/2022 @ 4:29 PM 3 days, 4 hours, 49 minutes 20093133 6/01/2022 @ 11:10 AM 6/04/2022 @ 4:29 PM 3 days, 5 hours, 19 minutes 20093142 6/01/2022 @ 9:30 AM 6/04/2022 @ 4:29 PM 3 days, 6 hours, 59 minutes 20093143 6/01/2022 @ 10:05 AM 6/04/2022 @ 4:29 PM 3 days, 6 hours, 24 minutes 20093144 6/01/2022 @ 9:40 AM 6/04/2022 @ 4:29 PM 3 days, 6 hours, 49 minutes 20093145 6/01/2022 @ 10:15 AM 6/04/2022 @ 4:29

PM 3 days, 6 hours, 14 minutes 20093146 6/01/2022 @ 9:50 AM 6/04/2022 @ 4:29 PM 3 days, 6 hours, 39 minutes 20093155 5/31/2022 @ 9:55 AM 6/04/2022 @ 4:29 PM 4 days, 6 hours, 34 minutes 20093161 5/31/2022 @ 10:35 AM 6/04/2022 @ 4:29 PM 4 days, 5 hours, 54 minutes 20093162 5/31/2022 @ 10:15 AM 6/04/2022 @ 4:29 PM 4 days, 6 hours, 14 minutes 20093163 5/31/2022 @ 9:55 AM 6/04/2022 @ 4:29 PM 4 days, 6 hours, 34 minutes 20093164 5/31/2022 @ 10:55 AM 6/04/2022 @ 4:29 PM 4 days, 5 hours, 34 minutes 20093165 5/31/2022 @ 9:43 AM 6/04/2022 @ 4:29 PM 4 days, 6 hours, 46 minutes 20093166 5/31/2022 @ 10:05 AM 6/04/2022 @ 4:29 PM 4 days, 6 hours, 24 minutes 20093167 5/31/2022 @ 11:05 AM 6/04/2022 @ 4:29 PM 4 days, 5 hours, 24 minutes 20093168 5/31/2022 @ 10:25 AM 6/04/2022 @ 4:29 PM 4 days, 6 hours, 4 minutes 20093171 5/31/2022 @ 1:20 PM 6/04/2022 @ 4:29 PM 4 days, 3 hours, 9 minutes 20093173 6/01/2022 @ 11:00 AM 6/04/2022 @ 4:29 PM 3 days, 5 hours, 29 minutes 20093218 6/01/2022 @ 10:50 AM 6/04/2022 @ 4:29 PM 3 days, 5 hours, 39 minutes 20093186 6/01/2022 @ 12:15 PM 6/04/2022 @ 4:29 PM 3 days, 4 hours, 14 minutes 2009318 6/01/2022 @ 12:30 PM 6/04/2022 @ 4:29 PM 3 days, 3 hours, 59 minutes c. Test run performed on June 7, 2022, 40 out of 100 specimens (20 pools) were older than 3 days: LAB ID# Collection Date/Time Date of Test Run Elapsed Time HIV IND88 5/31/2022 @ 1:27 PM 6/07/2022 @ 12:39 PM 7 days, 11 hours, 12 minutes HIV IND89 6/02/2022 @ 10:10AM 6/07/2022 @ 12:39 PM 5 days, 2 hours, 29 minutes HIV IND90 6/02/2022 @ 15:00 6/07/2022 @ 12:39 PM 4 days, 21 hours, 39 minutes HIV IND91 5/31/2022 @ 8:40 AM 6/07/2022 @ 12: 39 PM 7 days, 3 hours, 59 minutes HIV 2258 6/01/2022 @ 12:25 PM 6/07/2022 @ 12: 39 PM 6 days, 0 hours, 14 minutes HIV 2259 6/01/2022 @ 12:00 PM 6/07/2022 @ 12: 39 PM 6 days, 0 hours, 39 minutes HIV 2260 6/01/2022 @ 12:30 PM 6/07/2022 @ 12: 39 PM 6 days, 0 hours, 9 minutes HIV 2261 6/01/2022 @ 6:00 PM 6/07/2022 @ 12: 39 PM 5 days, 18 hours, 39 minutes HIV 2262 6/02/2022 @ 3:00 PM 6/07/2022 @ 12: 39 PM 4 days, 21 hours, 39 hours HIV 2263 6/02/2022 @ 12:30 PM 6/07/2022 @ 12: 39 PM 5 days, 0 hours, 9 minutes HIV 2264 6/02/2022 @ 3:30 PM 6/07/2022 @ 12: 39 PM 4 days, 21 hours, 9 minutes HIV 2265 6/02/2022 @ 5:00 PM 6/07/2022 @ 12: 39 PM 4 days, 19 hours, 39 minutes HIV 2266 6/03/2022 @ 10:00 AM 6/07/2022 @ 12:39 PM 4 days, 2 hours, 39 minutes HIV 2267 6/03/2022 @ 10:25 AM 6/07/2022 @ 12:39 PM 4 days, 2 hours, 14 minutes HIV 2268 6/03/2022 @ 13:30 6/07/2022 @ 12:39 PM 3 days, 23 hours, 9 minutes HIV 2269 6/03/2022 @ 9:45 AM 6/07/2022 @ 12:39 PM 4 days, 2 hours, 54 minutes HIV 2276 6/03/2022 @ 4:30 PM 6/07/2022 @ 12:39 PM 3 days, 20 hours, 9 minutes HIV 2277 6/03/2022 @ 2:30 PM 6/07/2022 @ 12:39 PM 3 days, 22 hours, 9 minutes HIV 2278 6/03/2022 @ 2:00 PM 6/07/2022 @ 12:39 PM 3 days, 22 hours, 39 minutes HIV 2279 6/03/2022 @ 1:00 PM 6/07/2022 @ 12:39 PM 3 days, 23 hours, 39 minutes HIV 2280 6/03/2022 @ 11:30 AM 6/07/2022 @ 12:39 PM 4 days, 1 hours, 9 minutes HIV 2281 6/03/2022 @ 10:30 AM 6/07/2022 @ 12:39 PM 4 days, 2 hours, 9 minutes HIV 2282 6/03/2022 @ 11:00 AM 6/07/2022 @ 12:39 PM 4 days, 1 hours, 39 minutes HIV 2283 6/03/2022 @ 2:50 PM 6/07/2022 @ 12:39 PM 3 days, 21 hours, 49 minutes HIV 2284 6/03/2022 @ 2:45 PM 6/07/2022 @ 12:39 PM 3 days, 21 hours, 54 minutes HIV 2285 6/03/2022 @ 7:40 PM 6/07/2022 @ 12:39 PM 3 days, 16 hours, 59 minutes HIV 2287 6/03/2022 @ 8:30 PM 6/07/2022 @ 12:39 PM 3 days, 16 hours, 9 minutes HIV 2288 6/03/2022 @ 9:35 AM 6/07/2022 @ 12:39 PM 4 days, 3 hours, 4 minutes HIV 2289 6/03/2022 @ 11:10 AM 6/07/2022 @ 12:39 PM 4 days, 1 hours, 29 minutes HIV 2290 6/03/2022 @ 11:45 AM 6/07 /2022 @ 12:39 PM 4 days, 0 hours, 54 minutes HIV 2291 6/03/2022 @ 12:10 PM 6/07 /2022 @ 12:39 PM 4 days, 0 hours, 29 minutes HIV 2292 6/03/2022 @ 12:40 PM 6/07 /2022 @ 12:39 PM 3 days, 23 hours, 59 minutes HIV 2293 6/03/2022 @ 1:00 PM 6/07 /2022 @ 12:39 PM 3 days, 23 hours, 39 minutes HIV 2294 6/03/2022 @ 1:40 PM 6/07 /2022 @ 12:39 PM 3 days, 22 hours, 59 minutes HIV 2295 6/03/2022 @ 2:05 PM 6/07 /2022 @ 12:39 PM 3 days, 22 hours, 34 minutes HIV 2296 6/03/2022 @ 2:41 PM 6/07

/2022 @ 12:39 PM 3 days, 21 hours, 58 minutes HIV 2297 6/03/2022 @ 3:35 PM 6/07 /2022 @ 12:39 PM 3 days, 21 hours, 4 minutes HIV 2298 6/03/2022 @ 4:15 PM 6/07 /2022 @ 12:39 PM 3 days, 20 hours, 24 minutes HIV 2299 6/03/2022 @ 5:12 PM 6/07 /2022 @ 12:39 PM 3 days, 19 hours, 27 minutes HIV 2300 6/03/2022 @ 7:35 PM 6/07 /2022 @ 12:39 PM 3 days, 17 hours, 4 minutes None of the above test's requisitions /test reports/worklists/worksheets indicated any of the specimens had been poured over into the SAT, or frozen, or the number of freeze thaw cycles. They were stamped with "Specimen Temperature Arrived Cold" (see D5311 V and D5317). 6. Interview with Testing personnel #3 on June 8, 2022 at 0915 hours confirmed specimens tested for HIV-1 and HIV-2 Ag-Ab that were non-reactive were then reflexed to pooled HIV-1 Qualitative testing. Interview with the Technical Supervisor #2, as listed on the CMS Form 209, on June 8 at 1340 hours acknowledged the reason to pour over the tubes was to prevent red blood cell contamination. Interview on June 9, 2022 at 1155 hours in the lab with testing personnel #3 confirmed all the tubes tested for the HIV-1 were received in the primary collection tube and transferred to a SAT for the pooled sample used in testing. 7. Surveyor observed on June 9, 2022 at 1155 hours all the racks from previous runs were stored in the refrigerator and contained samples stored in the primary collection tube. 8. Review of the test runs showed testing began May 31, 2022, and from May 31, 2022 to June 7, 2022 showed 610 specimens were tested. * The laboratory pooled 5 specimens per SAT for the test. KEY: SAT = Specimen Aliquot Tube PPT = Plasma Preparation Tube SST = Serum Separator Tube ACD = Acid Citrate Dextrose EDTA = Ethylenediaminetetraacetic acid HIV-1 = Human Immunodeficiency Type 1 III. Based on review of the laboratory's policy and procedure, observation, LIS (Laboratory Information System) TAT (Turn Around Time) query, test reports, and interview, the laboratory failed to ensure Covid samples were processed and lysed within 96 hours for three out of 982 samples reviewed. Findings follow. 1. Review of the Aptima SARS-CoV-2 Assay (Panther System) Standard Operating Procedure, version 1.5, May 2022, under Storage stated, "Specimens in VTM/UTM will be stored at 2 to 8 degrees Celsius for no more than 96 hours before being transferred into Hologic Specimen Lysis Tubes." 2. Surveyor observed on June 7, 2022 at 1100 hours, testing personnel #9 accessioning specimens into the Horizon LIMS using the High-speed Login where a field for "Turn Code" stated acceptability as "5 days from receipt". After obtaining a specimen Lab ID#, he transferred the sample from the Primary Specimen Container to the associated Hologic Specimen Lysis Tube. 3. Review of an LIS TAT query and patient test reports showed from 12/01/2021 - 06/04/2022, three specimens exceeded the 96 hours: Lab ID Date of collection Received/Accessioned in Lab Elapsed time a. 2201180008 01/14/2022 01/18/2022 @ 10:34 4 days, 10 hours, 34 minutes b. 2201180009 01/14/2022 01/18/2022 @10:40 4 days, 10 hours, 40 minutes c. 2202020046 01/28/2022 02/02/2022 @ 11:51 5 days, 11 hours, 51 minutes * Time of collection was not on the test requisitions and was entered as 00:00, midnight, refer to D5305. 4. Interview with the Technical Supervisor #2, as listed on the CMS Form 209, on June 8 at 1340 hours confirmed some specimens exceeded the 96-hour turnaround time. 5. Review of the LIS query showed a semi-annual test volume of 982 from Dec 1, 2021 - May 31, 2022. Key: VTM Viral Transport Media 41090 IV. Based on a review of the laboratory's procedure, receiving logs, and interview with the Biosafety Officer the laboratory failed to ensure the preanalytic storage requirements were met for three of three patient samples (sampling) received for Non-variola Orthopoxvirus and Orthopoxvirus testing. 1. A review of Dallas County Health and Human Services Health Alert revealed "Guidance for clinician suspecting monkeypox: 4. Specimens received at Dallas County LRN that are [greater than] 8C will be rejected." 2. A review of the receiving log revealed the laboratory did not have a system in place to ensure monkeypox specimens did not exceed 8C, as follows: Lab

	ID: 2206060001; Temp: Cold Lab ID: 2206040001; Temp: Cold Lab ID: 2206050001; Temp: Cold 3. In an interview on 06/09/2022 at 1343 and 1503 hours in the conference room, the Biosafety Officer explained the patient sample temperature is recorded as cold/frozen when received and the actual temperature is not taken on arrival. Word Key: LRN= Laboratory Response Network; C=degree Celsius 41687 V. Based on a review of the laboratory's Client Services Manual, surveyor observation, patient test records, and staff interview, it was revealed that the laboratory failed to ensure the temperature of four patient's blood specimens used for serology testing were maintained during transport on June 8, 2022 and June 9, 2022. Findings include: 1. A review of the laboratory's Client Services Manual (version 1.2, May 2022) revealed the following: "The Accessioning Section performs an initial inspection of the submitted specimens ensuring the following: a) Temperature of the specimen was maintained during shipping b) No expired, leaking, or broken collection containers are present c) Accompanying test requisitions are present" 2. Surveyor observation of the Accessioning Section on June 8, 2022 at 10:20 a.m. revealed a courier brought in a box from a facility in Mckinney, Texas. The box contained an ice pack, that was cold to the touch, and three bags with patient specimens inside (one bag contained urine specimens and the other two bags contained blood specimens). The accessioner used a thermal gun to obtain the temperature of one urine specimen from the bag, the temperature reading from that urine was 13.1 C. The accessioner then placed a sticker on each bag, indicating the following: - date received - time received - for the bag with the urine specimens, the temperature reading from one urine specimen (13.1 C) - for the bags with the blood specimens, "Specimen arrived: COLD" *The temperature of the blood specimens were not obtained. 3. Surveyor observation of the Accessioning Section on June 9, 2022 at 10:36 a.m. revealed a courier brought in specimens from a facility in Dallas, Texas. The courier brought in the specimens in a cooler with 2 ice packs that were frozen solid. The patient's specimens were contained in 3 racks, one rack for blood specimens, one rack for urine specimens, and a third rack for other Aptima specimens. The accessioner used a thermal gun to obtain the temperature of one urine specimen from the rack, the temperature reading from that urine was 19.6 C. The accessioner then placed the samples in the storage refrigerator. * The temperature of the blood specimens were not obtained. 4. A review of patient test records revealed the following 4 specimens from the above listed shipments were tested and the laboratory failed to ensure the temperature of the specimens were maintained during transport: Patient: JC08182002 Test: BioPlex Syphilis Antibody test and BioPlex HIV Ag-Ab test Patient: VP12311971 Test: BioPlex Syphilis Antibody test and BioPlex HIV Ag-Ab test Patient: PC12231989 Test: BioPlex Syphilis Antibody test and BioPlex HIV Ag-Ab test Patient: ME04221961 Test: BioPlex Syphilis Antibody test, Rapid Plasma Reagin, Qualitative and Quantitative tests 5. An interview with the quality manager on 6/9/22 at 1:30 p.m. in the laboratory, after review of the records, confirmed the above findings. Key: C = Degrees Celsius
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Client Services Manual and staff interview, it

	was revealed that the laboratory failed to define the acceptability criteria for "COLD" specimens in the Client Services Manual for 7 of 13 serology tests performed. Findings include: 1. A review of the laboratory's Client Services Manual (version 1.2, May 2022) revealed the following: a) Treponema pallidum Antibodies test "Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives COLD specimens." b) Rapid Plasma Reagin (RPR) Qualitative test "Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives COLD specimens." c) Rapid Plasma Reagin (RPR) Quantitative (TITER) test "Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives COLD specimens." d) Treponema pallidum- Particle Agglutination (TP-PA) test "Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives COLD specimens." e) HIV-1 and HIV-2 AG-AB Diagnostic Screen, 5th Gen. test "Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives COLD specimens." f) HIV Differentiation and Confirmation testing "Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives COLD specimens." g) HIV-1, NAAT Qualitative test "Transport specimens in an enclosed container with ice packs to ensure the Laboratory receives COLD specimens." 2. An interview with the quality coordinator on 6/8/22 at 1:30 p.m. in the conference room, after review of the records, confirmed that the laboratory does not have a defined acceptability criteria for "COLD" specimens received into the laboratory.
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 a review of the Serodia- TPPA instructions for use, the laboratory's policies, surveyor observation, patient test records, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's insturctions by not allowing the microplate to stand at room temperature for two hours before reading 12 of 12 patient's Treponema pallidum particle agglutination (TPPA) results. Findings include: 1. A review of the Serodia- TPPA instructions for use (Sheet 020912.indd) revealed the following: "Mix the contents of the well thoroughly (for approximately 30 seconds) using a plate mixer (automatic vibratory shaker). DO NOT USE A ROTATOR. Then cover the plate with an empty plate or microplate cover, and let stand at room temperature (15-30 C) for 2 hours before reading." 2. A review of the laboratory's policy titled "Treponema Pallidum- Particle Agglutination" revealed the following: "Cover the plate with an empty plate or microplate cover and let stand at room temperature (15-30 C) for 2 hours before reading." 3. Surveyor observation of the serology laboratory on 6/7/22 at 1:30 p.m. revealed testing person #6 was performing the Serodia- TPPA test. Testing person #6 finished setting up the plate at 1:50 p.m.. Testing person #6 did not note the time or set a timer. When questioned about how long the plate with the patient's specimens stands before it can be read, testing person #6 said "as long as the controls work, it can be read." 4. Further observation of the serology laboratory on 6/7/22 at 3:29 p.m. revealed testing person #6 had read and notated the following 12 patient's results on the TPPA worksheet and the plate had only been standing for 1 hour and 39 minutes (21 minutes short of the

	required 2 hour timeframe): Lab Numbers: 974142 801709 1010901 1003439 2392 2406 2411 2414 2423 2426 2433 2449 5. An interview with testing person #6 (as indicated on the CMS 209 form) on 6/7/22 at 2:40 p.m. in the serology laboratory, after review of the records, confirmed the above findings. 45469 II. Based on observation, review of manufacturer's instructions for use, and confirmed in an interview, the laboratory failed to follow the manufacturer's instructions for the handling of the BioPlex 2200 HIV Ag-Ab controls observed on 6/8/2022. The findings include: 1. Surveyor observed, on 6/8/2022 at 08:35 hours in the laboratory, testing person (TP) 13 press a kimwipe to the top of the control vials. Surveyor queried as to why, and TP13 informed them that it was to pop the bubbles at the top of the tube, prior to loading onto the BioPlex 2200 chemistry analyzer. 2. Review of the BioPlex 2200 HIV Ag-Ab Control Set instructions for use, section "Procedure" had the following instructions: "Before sampling, gently mix to ensure homogeneity. If foam or bubbles are observed, centrifuge controls at 10,000 RC (relative centrifugal force) for 5 minutes. Ensure that all bubbles are removed prior to use." 3. Surveyor queried 6/8/2022 at 10:33 hours, in the laboratory, if there was a centrifuge available to centrifuge the control vials as indicated by the instructions for use and TP13 confirmed that there was no centrifuge available. 4. In an interview on 6/8/202 at 11: 15 hours, in the conference room, the quality manager confirmed that the laboratory was not following the manufacturer's instructions for the handling of bubbles or foam in the controls prior to use.
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 a review of the laboratory's policies, surveyor observation, patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of monitoring the refrigerator temperature, where patient's specimens were stored, for 12 of 12 months in 2021. Findings include: 1. A review of the laboratory's policies titled 'BioPlex 2200 Syphilis Total Assay' and 'BioPlex 2200 HIV Ag-Ab Assay' revealed the following specimen storage requirements: "Refrigerated serum (2-8 C) can be stored for up to SEVEN days past initial collection AND centrifugation." 2. Surveyor observation of room 108 on 6/9/22 at 10:50 a.m. revealed a refrigerator where patient's specimens for the BioPlex Syphilis Antibody test and HIV Ag-Ab testing were being stored. 3. Further observation revealed the refrigerator was not being monitored with a Smart View meter. 4. The quality coordinator was asked on 6/9/22 at 10:00 a.m. for documentation of monitoring the refrigerator temperature for the 12 months (January to December) in 2021. No documentation was provided. 5. A review of patient test records revealed the following 4 patient's samples were stored in that refrigerator and then tested without ensuring the temperature requirements for patient's specimen storage were met: Patient: 867804 Test: BioPlex Syphilis Antibody Patient: 867668 Test: BioPlex HIV Ag-Ab Patient: 867780 Test: BioPlex Syphilis Antibody Patient: 867701 Test: BioPlex HIV Ag-Ab 6. An interview

	with the quality coordinator on 6/9/22 at 10:00 a.m. in the conference room, confirmed that the temperature of the refrigerator in room 108 was not being monitored.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of instructions for use, laboratory documents, the Centers for Medicare and Medicaid (CMS) form 116, and confirmed in interview, the laboratory failed to define a function check protocol that ensures equipment test performance for the ASI Rapid Plasma Reagin (RPR) Card Test for five of five RPR card rotators in 2021. Findings included: 1. In a tour of the laboratory, on 6/6/2022 13:30 hours, the following five automatic card rotators were observed in use for RPR testing. Three rotators in the stat laboratory: "A" - Serial number: 900120521 "B" - Serial number: 900120770 "C" - Serial number: 0120256 Two rotators in the main laboratory: Serial number: 1358040589649 Serial number: 900120771 2. Review of the "ASI RPR Card Test for Syphilis" instructions for use, section "Assay Protocol - Qualitative" had the following instructions: "5. Place the card on an automatic rotator and cover to maintain humidity. Rotate at 100 +/- 5 rpm for 8 minutes (7 minutes 50 seconds to 8 minutes 30 seconds)." 3. Surveyor queried the quality manager (QM) on 6/7/2022 at 11:30 hours, in the conference room, for function check documentation that the rotator's speed and timers were accurate, and none was provided. The QM stated that they did not have a defined protocol for documenting the function checks as required by the manufacturer. 4. Review of the CMS form 116, section VIII "Non-Waived Testing" listed the annual test volume for "Diagnostic Immunology" at 127,365. 5. In an interview on 6/7/2022 at 13:55 hours, in the conference room, the QM confirmed that the laboratory had not been verifying the accuracy of the rotator speed or rotator timers for all five rotators in use for RPR testing.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, manufacturer's instructions, laboratory records and interview, the laboratory failed to perform background calibrations on the Applied Biosystems (ABI) 7500 Fast Dx Real-time PCR instrument for 18 of 18 months reviewed. Findings follow. 1. Review of the CDC Influenza SARS-CoV-2 (FLU SC2) Multiplex Assay SOP (Standard Operating Procedure), Version 1.5, May 2022, under Scope and Objective stated, "The Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay is a real-time RT-PCR multiplexed test intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, Influenza A virus, and /or influenza B virus nucleic acid". The use of the ABI 7500 PCR instrument is described at "11.6 Create a Run Template on the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument", and "11.8 Running a test". 2. Review of the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument Instructions for Use, 4406991, January 2012, under Performing the Background Calibration at Background Fluorescence stated, "Fluorescence data collected by the Applied Biosystems 7500 Fast dx Real-Time PCR instrument includes a fluorescent signal inherent io the instrument, commonly referred to as background fluorescence. Background fluorescence is a composite signal found in all spectral data. This signal consists of fluorescence from several sources, including: Background electronic signal Contaminants in the sample block The plastic consumables (plates and caps). Under the chapter Maintaining the Instrument at Recommended Maintenance Schedule, for Monthly Maintenance Tasks stated, "Perform a background calibration." 3. Background Calibrations were requested on June 7, 2022 at 1350 hours. 4. Review of laboratory records showed no background calibrations were performed. 5. Interview with the Technical Supervisor #2, as listed on the CMS Form 209, on June 7 at 1400 hours confirmed they do not perform background calibrations. KEY: PCR = polymerase chain reaction
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory failed to ensure that two of two comparison studies were performed as required in 2021 on the following systems that perform the same tests: a) Biotech Syphilis Health Check b) BioPlex 2200 Syphilis Total Assay Findings include: 1. A review of the laboratory's records revealed no documentation of, twice a year, performing comparison studies in 2021 between the following systems used for testing syphilis IgG and IgM antibodies: a) Biotech Syphilis Health Check b) BioPlex 2200 Syphilis Total Assay 2. An interview with the quality manager on 6/9/22 at 9:22 a.m. in the conference room, after review of the records, confirmed that the comparison studies had not been done.
D5781	CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
I. Based on a review of quality control (QC) records, laboratory policy, and confirmed in interview, the laboratory failed to document corrective action for the HIV Ab-Ag Assay, on the BioPlex 2200 analyzer, for 13 out of 14 QC performance issues reviewed from January 2022 to March 2022. The findings include: 1. Review of the HIV Ab-Ag QC records from January to March 2022 had the following 13 QC errors in which corrective action to achieve acceptable QC results was not documented: 1/6/2022: QC_HIV_875_L03: HIV-1 AB - QC Warning QC_HIV_875_L03: HIV-1 M Ab - QC Warning 1/10/2022: QC_HIV_882_L03: HIV-1M Ab - Sample Processing Error QC_HIV_882_L03: HIV-1 O Ab - Sample Processing Error QC_HIV_882_L03: HIV-2 Ab - Sample Processing Error 1/13/2022: QC_HIV_894_L03: HIV-1 Ab - QC Warning QC_HIV_894_L03: HIV-1 M Ab - QC Warning 1/21/2022: QC_HIV_918_L03: HIV-2 Ab - QC Failed 2/9/2022: QC_HIV_958_L03: HIV-2 Ab - QC Failed QC_HIV_957_L03: HIV-2 Ab - QC Failed 3/8/2022: QC_HIV_1017_L03: HIV- Ab - QC Warning 3/11/2022: QC_HIV_1026_L03: HIV-1 Ab - QC Warning HI QC_HIV_1026_L03: V-1 O Ab - QC Warning 2. Review of the laboratory policy titled "Bioplex 2200 HIV AG-AB Assay" did not include instructions for the documentation of corrective action when QC acceptability was outside of performance specifications. 3. Surveyor queried technical supervisor (TS) 5 on 6/8/2022 at 08:43 hours, in the laboratory, for documentation of the corrective action for the above QC issues, in which the laboratory detailed the steps to achieve acceptable QC, and none was provided. 4. In an interview on 6/8/2022 at 11:45 hours, in the conference room, the quality manager confirmed that the laboratory did not document the steps of corrective action when QC acceptability was outside of performance acceptability for the HIV Ag-Ab on the BioPlex 2200 analyzer. II. Based on a review of calibration records and confirmed in an interview the laboratory failed to document corrective action for the HIV Ag-Ab assay on the BioPlex 2200 analyzer for calibration failures for three out of six calibrations reviewed from January 2022 to June 2022. The findings include: 1. Review of the calibration records from January to June 2022 had the following three calibration failures for HIV on the BioPlex 2200-0232. 1/28/2022 - HIV Calibration - Failed 4/4/2022 - HIV Calibration - Failed 6/3/2022 - HIV Calibration - Failed 2. Review of the laboratory policy titled "Bioplex 2200 HIV AG-AB Assay" did not include instructions for the documentation of corrective action when QC acceptability was outside of performance specifications. 3. Surveyor queried technical supervisor (TS) 5 on 6/8/2022 at 08:43 hours, in the laboratory, for documentation of the corrective action for the above calibration failures, in which the laboratory detailed the steps to achieve a passing calibration, and none was provided. 4. In an interview on 6/8/2022 at 11:45 hours, in the conference room, the quality manager confirmed that the laboratory did not document the steps of corrective action for failed HIV Ag-

	Ab calibration on the BioPlex 2200 analyzer. III. Based on a review of laboratory instructions for use, laboratory quality control records, and confirmed in interview, the laboratory failed to document corrective action for 16 out of 61 days the reagent temperature was out of performance specifications for the ASI Rapid Plasma Reagin (RPR) Card Test for Syphilis reviewed for February, March, and May 2022. The findings include: 1. Review of the "ASI RPR Card Test for Syphilis" instructions for use, section "Preparation for the Assay" stated: "Allow all reagents and samples to warm to room temperature (20-30 (degrees) Celsius (C))." And Section "Limitations of the procedure" stated: "7. Temperature of the reagents and samples is crucial to test outcome; it should be between 20-30(degrees)C." 2. Review of the "ASI RPR Quality Control Worksheet" had the defined acceptable temperature range at 25(degrees)C +/- 5(degrees)C with the following 16 days reagent temperatures out of established performance specifications without corrective action documented in February, March, and May 2022: February 2022: 4 days 2/7/2022 Carbon Antigen Suspension: 18 (degrees) C Control ++: 19(degrees) C Control +: 19(degrees) C Nonreactive: 18 (degrees) C 2/8/2022 Control +: 19(degrees) C Nonreactive: 19(degrees) C 2/9/2022 Carbon Antigen Suspension: 19(degrees) C Control ++: 19(degrees) C Control +: 18 (degrees) C Nonreactive: 17(degrees) C 2/11/2022: Carbon Antigen Suspension: 19 (degrees) C March 2022: 6 Days 3/3/2022 Control +: 19(degrees) C 3/4/2022 Control ++: 19(degrees) C Control +: 19(degrees) C Nonreactive: 19(degrees) C 3/22/2022 Control ++: 19(degrees) C Control +: 19(degrees) C 3/24/2022: Control ++: 19 (degrees) C Control +: 18(degrees) C Nonreactive: 18(degrees) C 3/25/2022: Carbon Antigen Suspension: 19(degrees) C Control ++: 18(degrees) C Control +: 18(degrees) C Nonreactive: 18(degrees) C 3/30/2022 Carbon Antigen Suspension: 19(degrees) C May 2022: 6 Days 5/4/2022 Carbon Antigen Suspension: 19(degrees) C Control ++: 19 (degrees) C Control +: 19 (degrees) C Nonreactive: 19 (degrees) C 5/5/2022: Control ++: 19(degrees) C 5/6/2022: Carbon Antigen Suspension: 19(degrees) C 5/16 /2022: Nonreactive: 19(degrees) C 5/17/2022: Control ++: 19(degrees) C Control +: 19(degrees) C Nonreactive: 19(degrees) C 5/20/2022: Nonreactive: 19(degrees) C 3. Surveyor queried technical supervisor (TS) 5, 6/8/2022 at 09:10 hours, in the laboratory, as to the steps taken when the reagents temperatures are out of the specified range (20-30 degrees C). TS 5 said they wait until the temperatures are in range before testing. 4. In an interview on 6/8/2022 at 11:54 hours, in the conference room, the quality manager (QM) confirmed that the laboratory was not documenting the corrective action for reagents when they fail to meet the temperature performance specifications.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: I. Based on a review of the Laboratory Response Network (LNR) procedure for detection of non-variola Orthopoxvirus DNA, patient final reports, and an interview

	with the Biosafety Officer, the laboratory failed to include the correct result interpretation for reporting presumptive positive, inconclusive, and negative test results for three of three patients (random sampling). 1. A review of the Laboratory Response Network procedure "Detection of Non-variola Orthopoxvirus DNA by Fluorogenic 5' Nuclease Assay using the Applied Biosystems 7500 Fast DX Real-time PCR System" Document #: LNR-1108, Revision #5, Effective Date: 4/4/2019 revealed on page 21 ... "7. Reporting/action ...c. Report presumptive positive results as 'Non-variola Orthopoxvirus DNA detected by real-time PCR'; e. Report inconclusive results as 'Inconclusive for non-variola Orthopoxvirus DNA by Real-time PCR'; f. Report negative results as 'non-variola Orthopoxvirus DNA not detected by real-time PCR.'" 2. A review of patient final reports from June 2022 (sampling) revealed: Lab ID: 2206060001; Result: Non-variola orthopoxvirus DNA detected Lab ID: 2206040001; Result: Inconclusive for the presence of non-variola orthopoxvirus DNA Lab ID: 2206050001; Result: No non-variola orthopoxvirus DNA detected The laboratory's result interpretation was not identical to the procedure interpretation. 3. An interview with the Biosafety Officer on 06/07/2022 at 1343 hours in the conference room confirmed these findings. II. Based on a review of the Laboratory Response Network (LNR) procedure for detection of Orthopoxvirus DNA, patient final reports, and an interview with the Biosafety Officer, the laboratory failed to include the appropriate result interpretation for reporting presumptive positive and negative test results for two of three patients (random sampling). 1. A review of the LRN procedure "Detection of Orthopoxvirus DNA using the AB 7500 Fast or Fast Dx Real-time PCR System", Document # LRN-1105, Revision #03, Effective Date: 12/5 /2014 revealed, "7. Reporting/action ...c. Report presumptive positive results as 'Orthopoxvirus DNA detected by real-time PCR.', d. Report Negative results as 'No Orthopoxvirus DNA detected by real-time PCR.'" 2. A review of patient final reports from June 2022 (sampling) revealed: Lab ID: 2206060001; Result: Orthopoxvirus DNA detected Lab ID: 2206050001; Result: No Orthopoxvirus DNA detected The laboratory's result interpretation was not identical to the procedure interpretation. 3. An interview with the Biosafety Officer on 06/07/2022 at 1343 hours in the conference room confirmed these findings. Word Key: PCR=polymerase chain reaction; DNA=deoxyribonucleic acid
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, the laboratory's policy and procedure, observation, test requisitions/test reports, worklists, worksheets, LIS TAT query, LIS query, receiving logs, and interview, the laboratory director failed to ensure the laboratory performed quality laboratory services for all aspects of test performance, including the preanalytic phase of testing. Findings follow. 1. The laboratory failed to ensure the test requisition for Covid samples included the time of specimen collection for six out of six samples reviewed (see D5305). 2. The laboratory failed to ensure HIV-1 specimens were tested on the Panther System within five days of collection when stored at 2 to 8 degrees Celsius for 19 out of 415 specimens reviewed (refer to D5311 I). 3. The laboratory failed to ensure HIV-1 specimens tested on the Panther

	System were transferred to the SAT within 3 days of collection when stored at 2 to 8 degrees Celsius for up to five days after collection, or frozen for storage up to 90 days to allow for testing for 88 out of 415 specimens (refer to D5311 II). 4. The laboratory failed to ensure Covid samples tested on the Panther System were processed and lysed within 96 hours for three out of 982 samples reviewed (refer to D5311 III). 5. The laboratory failed to ensure the preanalytic storage requirements were met for three of three patient samples (sampling) received for Non-variola Orthopoxvirus and Orthopoxvirus testing (refer to D5311 IV). 6. The laboratory failed to ensure the temperature of patient's blood specimens used for serology testing were maintained during transport (refer to D5311 V). 7. The laboratory failed to define the acceptability criteria for "COLD" specimens in the Client Services Manual (refer to D5317). KEY: LIS = Laboratory Information System TAT = Turn Around Time HIV-1 = Human Immunodeficiency Type 1 SAT = Specimen Aliquot Tube
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, the laboratory's policy and procedure, observation, test requisitions/test reports, worklists, worksheets, LIS TAT query, receiving logs, and interview, the technical supervisor failed to ensure the technical and scientific oversight of the laboratory. Findings follow. 1. The laboratory failed to ensure HIV-1 specimens were tested on the Panther System within five days of collection when stored at 2 to 8 degrees Celsius for 19 out of 415 specimens reviewed (refer to D5311 I). 2. The laboratory failed to ensure HIV-1 specimens tested on the Panther System were transferred to the SAT within 3 days of collection when stored at 2 to 8 degrees Celsius for up to five days after collection, or frozen for storage up to 90 days to allow for testing for 88 out of 415 specimens (refer to D5311 II). 3. The laboratory failed to ensure Covid samples tested on the Panther System were processed and lysed within 96 hours for three out of 982 samples reviewed (refer to D5311 III). 4. The laboratory failed to ensure the preanalytic storage requirements were met for three of three patient samples (sampling) received for Non-variola Orthopoxvirus and Orthopoxvirus testing (refer to D5311 IV). 5. The laboratory failed to ensure the temperature of patient's blood specimens used for serology testing were maintained during transport (refer to D5311 V). 6. The laboratory failed to define the acceptability criteria for "COLD" specimens in the Client Services Manual (refer to D5317). KEY: LIS = Laboratory Information System TAT = Turn Around Time HIV-1 = Human Immunodeficiency Type 1 SAT = Specimen Aliquot Tube