Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0682457	11/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Bayside Community Hospital	200 Hospital Drive, Anahuac, 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 representative(s) at the exit conference. The facility representative(s) 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 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 CMS Southern Operations Branch-Dallas for referral to the Office of 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: Based on review of the manufacturer instructions for use for the ST AIA-PACK PA for quantitative measurement of prostate specific antigen (PSA), random review of patient records from January to November of 2022 and staff interview, it was determined the laboratory failed to follow manufacturer indications for patient age for 10 of 64 patients whose records were reviewed. Findings included: 1. Review of the manufacturer instructions for use (document 1002871001-106G) for the ST AIA-PACK PA for measurement of PSA revealed: "NAME AND INTENDED USE ... This device is indicated for measurement of serum PSA in conjunction with Digital

	Rectal Examination (DRE) as an aid in detection of prostate cancer (CaP) in men fifty years of age or older. This device is further indicated for the serial measurement of PSA in human serum or heparinized plasma to be used as an aid in management of patients with prostatic cancer." 2. Random review of patient records from January to November of 2022 revealed the following patients were tested outside of the age requirements, who did not have a diagnosis of cancer: Patient#: 10187351 Age: 43 Tested: 01/15/2022 PSA result: 0.40 ng/mL (nanograms per milliliter) Patient#: 10187457 Age: 44 Tested: 01/17/2022 PSA result: 0.80 ng/mL Patient#: 10187490 Age: 37 Tested: 01/18/2022 PSA result:0.50 ng/mL Patient#: 10198473 Age: 46 Tested: 07/15/2022 PSA result: 0.90 ng/mL Patient#: 10205000 Age: 31 Tested: 11/04 /2022 PSA result: 0.40 ng/mL Patient#: 10205125 Age: 49 Tested: 11/07/2022 PSA result: 0.90 ng/mL Patient#: 10205153 Age: 44 Tested: 11/07/2022 PSA result: 0.90 ng/mL Patient#: 10205112 Age: 34 Tested: 11/07/2022 PSA result: 0.60 ng/mL Patient#: 10205217 Age: 43 Tested: 11/08/2022 PSA result: 0.40 ng/mL Patient#: 10205204 Age: 47 Tested: 11/08/2022 PSA result: 5.20 ng/mL In an interview on 11 /21/2022 at 1400 hours in the office, the laboratory's General Supervisor number 1 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Vitros 350 chemistry analyzer's Maintenance and Diagnostics Guide, review of the laboratory's maintenance logs for the Vitros 350 chemistry analyzer for October and November of 2022, review of patient test records for the same interval and staff interview it was determined the laboratory failed to document following manufacturer instructions for changing instrument's Immuno-Wash Fluid Reservoir every 72 hours on 7 of 7 days the change was required while patient testing was performed. Findings included: 1. Review of the Maintenance and Diagnostics Guide for the VITROS 350/250 Chemistry Systems (document 994132UC, version 2.0, page 2-24) revealed: "Periodic Maintenance ... You must change the Immuno-Wash Fluid Reservoir at least every 72 hours..." 2. Review of the laboratory's maintenance logs for the Vitros 350 chemistry analyzer for October and November of 2022 revealed the following 7 of 7 days change of the instrument's Immuno-Wash Fluid Reservoir was required but was not documented, while patient testing was ongoing: Test Date: 09/04/2022 Date of last reservoir change: 09/01/2022 Time elapsed from last reservoir change: 72 hours Patient number: 10201357 Analyte: Alcohol Test Date: 09/05/2022 Date of last reservoir change: 09/01/2022 Time elapsed from last reservoir change: 96 hours Patient number: 10201357 Analyte: Alcohol Test Date: 09/07/2022 Date of last reservoir change: 09/01/2022 Time elapsed from last reservoir change: 144 hours Patient number: 10201513 Analyte: Alcohol Test Date: 09/19/2022 Date of last reservoir change: 09/16/2022 Time elapsed from last reservoir change: 72 hours Patient number: 10202045 Analyte: Digoxin Test Date: 09/20/2022 Date of last reservoir change: 09/16/2022 Time elapsed from last reservoir change: 96 hours Patient number: 10202306 Analyte: Alcohol Test Date: 09/28/2022 Date of last reservoir change: 09/22/2022 Time elapsed from last reservoir change: 144 hours Patient number: 10202750 Analyte: Alcohol Test Date: 10/21/2022 Date of last reservoir change:10/16/2022 Time elapsed

	from last reservoir change: 120 hours Patient numbers: 10204167 and 10204172 Analytes: Digoxin and Dilantin 3. In an interview on 11/21/2022 at 1430 hours in the office, the laboratory's General Supervisor number 1 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory's policies, review of laboratory's calibration and calibration verification records for 2021 and 2022 for the Ortho Vitros 350 chemistry analyzer and staff interview, it was determined the laboratory failed to document calibration verification for the electrolyte (Sodium, Potassium and Chloride) analytes at least every 6 months for 1 of 3 calibration verification intervals reviewed. Findings included: 1. Review of laboratory's policy "Laboratory Department Quality Assurance" (effective June 28, 2019), page 2, revealed: "Verify calibrations performance at frequency indicated by the manufacturer or every six months, whichever is more frequent." 2. Review of laboratory's calibration records for 2021 and 2022 for the Ortho Vitros 350 chemistry analyzer revealed the laboratory used 2 calibrators for the Sodium, Potassium and Chloride analytes, making every 6 months' calibration verification a requirement. 3. Review of laboratory's Sodium, Potassium and Chloride calibration verification records for 2021 and 2022 revealed calibration verification was performed as follows: Calibration verification date: 01/11/2021 Next calibration verification date: 07/09/2021 Interval elapsed: 6 months Calibration verification date: 07/09/2021 Next calibration verification date: 01/18/2022 Interval elapsed: 6 months Calibration verification date: 01/18/2022 Next calibration verification date: 09/29/2022 Interval elapsed: 8 months 4. In an interview on 11/21 /2022 at 1430 hours in the office, the laboratory's General Supervisor number 1 (as defined on submitted Form 209), after review of the data, confirmed the 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 the surveyor's direct observation, the laboratory's records, QC records from May to November 2022, patient records, and confirmed in an interview found the laboratory failed to perform qualitative QC to include a positive and a negative material prior to patient testing for one of one BD Max instrument for three of three test panels: SARS-CoV-2, CT/GC/TV assay, and vaginal panel. The findings were: 1. Review of the laboratory's records revealed the BD Max instrument was installed on 5 /12/22. 2. The surveyor's direct observation on 11/21/22 at 10:45 am in the lab revealed the laboratory performed three tests on BD Max instrument (SN: CT2647). SARS-CoV-2 CT/GC/TV assay Vaginal Panel including C. krusei, C. glabrata, and Candida group (C. albicans, C. parapsilosis, C. tropicalis, C. dubliniensis) 3. Review of patient records revealed three tests above were reported as positive or negative. Therefore, all three tests above were qualitative procedure. 2. Review the laboratory's QC records from May to November, 2022 revealed the following dates did not have documentation of qualitative QC to include a positive and a negative QC material prior to patient testing. Test assay/panel: SARS-CoV-2 8/9/22 to 8/22/22 9/14/22 to 9 /25/22 10/17/22 to 10/20/22 Test assay/panel: CT/GC/TV assay 8/3/22 to 8/22/22 9/13 /22 to 9/25/22 11/2/22 to 11/10/22 Test assay/panel: Vaginal Panel 7/11/22 to 7/19/22 8/10/22 to 8/22/22 9/30/22 to 10/11/22 11/2/22 to 11/16/22 3. Review of the laboratory's patient records for the above dates revealed 167 patient testing were performed. 7/11/22 Patient ID: 10198270 Test performed: Vaginal Panel 7/12/22 Patient ID: 10198292 Test performed: Vaginal Panel 7/12/22 Patient ID: 10198203 Test performed: Vaginal Panel 7/12/22 Patient ID: 10198257 Test performed: Vaginal Panel 7/13/22 Patient ID: 10198239 Test performed: Vaginal Panel 7/13/22 Patient ID: 10198298 Test performed: Vaginal Panel 7/13/22 Patient ID: 10198347 Test performed: Vaginal Panel 7/13/22 Patient ID: 10198345 Test performed: Vaginal Panel 7/14/22 Patient ID: 10198358 Test performed: Vaginal Panel 7/14/22 Patient ID: 10198380 Test performed: Vaginal Panel 7/15/22 Patient ID: 10198453 Test performed: Vaginal Panel 7/15/22 Patient ID: 10198504 Test performed: Vaginal Panel 7/15/22 Patient ID: 10198503 Test performed: Vaginal Panel 7/19/22 Patient ID: 10198603 Test performed: Vaginal Panel 7/19/22 Patient ID: 10198705 Test performed: Vaginal Panel 8/3/22 Patient ID: 10199471 Test performed: CT/GC/TV assay 8/6/22 Patient ID: 10199634 Test performed: CT/GC/TV assay 8/8/22 Patient ID: 10199686 Test performed: CT/GC/TV assay 8/9/22 Patient ID: 10199779 Test performed: SARS-CoV-2 8/9/22 Patient ID: 10199715 Test performed: CT/GC/TV assay 8/9/22 Patient ID: 10199732 Test performed: CT/GC/TV assay 8/9/22 Patient ID: 10199733 Test performed: CT/GC/TV assay 8/10/22 Patient ID: 10199869 Test performed: SARS-CoV-2 8/10/22 Patient ID: 10199846 Test performed: SARS-CoV-2 8/11/22 Patient ID: 10199877 Test performed: SARS-CoV-2 8/11/22 Patient ID: 10199993 Test performed: Vaginal Panel 8/12/22 Patient ID: 10199953 Test performed: SARS-CoV-2 8/12/22 Patient ID: 10199961 Test performed: SARS-CoV-2 8/12/22 Patient ID: 10199962 Test performed: SARS-CoV-2 8/12/22 Patient ID: 10199958 Test performed: Vaginal Panel 8/12/22 Patient ID: 10199959 Test performed: Vaginal Panel 8/12/22 Patient ID: 10199960 Test performed: Vaginal Panel 8/12/22 Patient ID: 10199957 Test performed: Vaginal Panel 8/12/22 Patient

ID: 10199999 Test performed: Vaginal Panel 8/12/22 Patient ID: 10200003 Test performed: Vaginal Panel 8/13/22 Patient ID: 10200023 Test performed: Vaginal Panel 8/13/22 Patient ID: 10200022 Test performed: Vaginal Panel 8/14/22 Patient ID: 10200045 Test performed: SARS-CoV-2 8/15/22 Patient ID: 10200094 Test performed: CT/GC/TV assay 8/15/22 Patient ID: 10200128 Test performed: CT/GC /TV assay 8/15/22 Patient ID: 10200130 Test performed: CT/GC/TV assay 8/15/22 Patient ID: 10200096 Test performed: Vaginal Panel 8/15/22 Patient ID: 10200097 Test performed: Vaginal Panel 8/15/22 Patient ID: 10200101 Test performed: Vaginal Panel 8/16/22 Patient ID: 10200190 Test performed: CT/GC/TV assay 8/16/22 Patient ID: 10200155 Test performed: CT/GC/TV assay 8/16/22 Patient ID: 10200157 Test performed: CT/GC/TV assay 8/16/22 Patient ID: 10200135 Test performed: Vaginal Panel 8/16/22 Patient ID: 10200130 Test performed: Vaginal Panel 8/16/22 Patient ID: 10200128 Test performed: Vaginal Panel 8/16/22 Patient ID: 10200190 Test performed: Vaginal Panel 8/16/22 Patient ID: 10200155 Test performed: Vaginal Panel 8/17/22 Patient ID: 10200212 Test performed: CT/GC/TV assay 8/17/22 Patient ID: 10200214 Test performed: CT/GC/TV assay 8/17/22 Patient ID: 10200263 Test performed: CT/GC/TV assay 8/17/22 Patient ID: 10200269 Test performed: CT/GC /TV assay 8/17/22 Patient ID: 10200270 Test performed: CT/GC/TV assay 8/17/22 Patient ID: 10200221 Test performed: Vaginal Panel 8/17/22 Patient ID: 10200212 Test performed: Vaginal Panel 8/17/22 Patient ID: 10200214 Test performed: Vaginal Panel 8/17/22 Patient ID: 10200270 Test performed: Vaginal Panel 8/17/22 Patient ID: 10200269 Test performed: Vaginal Panel 8/17/22 Patient ID: 10200263 Test performed: Vaginal Panel 8/17/22 Patient ID: 10200261 Test performed: Vaginal Panel 8/17/22 Patient ID: 10200249 Test performed: Vaginal Panel 8/18/22 Patient ID: 10200244 Test performed: CT/GC/TV assay 8/18/22 Patient ID: 10200351 Test performed: CT/GC/TV assay 8/18/22 Patient ID: 10200294 Test performed: SARS-CoV-2 8/18/22 Patient ID: 10200300 Test performed: SARS-CoV-2 8/18/22 Patient ID: 10200244 Test performed: Vaginal Panel 8/18/22 Patient ID: 10200351 Test performed: Vaginal Panel 8/19/22 Patient ID: 10200379 Test performed: CT/GC/TV assay 8/19/22 Patient ID: 10200307 Test performed: CT/GC/TV assay 8/19/22 Patient ID: 10200379 Test performed: Vaginal Panel 8/22/22 Patient ID: 10200499 Test performed: CT/GC/TV assay 8/22/22 Patient ID: 10200496 Test performed: CT/GC /TV assay 8/22/22 Patient ID: 10200499 Test performed: Vaginal Panel 8/22/22 Patient ID: 10200496 Test performed: Vaginal Panel 9/13/22 Patient ID: 10201829 Test performed: CT/GC/TV assay 9/14/22 Patient ID: 10201854 Test performed: CT /GC/TV assay 9/14/22 Patient ID: 10201896 Test performed: CT/GC/TV assay 9/15 /22 Patient ID: 10201994 Test performed: SARS-CoV-2 9/15/22 Patient ID: 10201997 Test performed: SARS-CoV-2 9/15/22 Patient ID: 10201934 Test performed: CT/GC/TV assay 9/15/22 Patient ID: 10201893 Test performed: CT/GC /TV assay 9/15/22 Patient ID: 10201988 Test performed: CT/GC/TV assay 9/16/22 Patient ID: 10202015 Test performed: SARS-CoV-2 9/16/22 Patient ID: 10202053 Test performed: SARS-CoV-2 9/16/22 Patient ID: 10201998 Test performed: CT/GC /TV assay 9/17/22 Patient ID: 10202098 Test performed: SARS-CoV-2 9/17/22 Patient ID: 10202101 Test performed: CT/GC/TV assay 9/19/22 Patient ID: 10202161 Test performed: CT/GC/TV assay 9/19/22 Patient ID: 10202172 Test performed: CT /GC/TV assay 9/20/22 Patient ID: 10202225 Test performed: SARS-CoV-2 9/20/22 Patient ID: 10202242 Test performed: SARS-CoV-2 9/20/22 Patient ID: 10202217 Test performed: CT/GC/TV assay 9/21/22 Patient ID: 10202335 Test performed: SARS-CoV-2 9/21/22 Patient ID: 10202342 Test performed: CT/GC/TV assay 9/21 /22 Patient ID: 10202300 Test performed: CT/GC/TV assay 9/21/22 Patient ID: 10202326 Test performed: CT/GC/TV assay 9/22/22 Patient ID: 10202366 Test performed: SARS-CoV-2 9/22/22 Patient ID: 10202369 Test performed: CT/GC/TV assay 9/22/22 Patient ID: 10202371 Test performed: CT/GC/TV assay 9/22/22 Patient

	ID: 10202375 Test performed: CT/GC/TV assay 9/22/22 Patient ID: 10202404 Test performed: CT/GC/TV assay 9/22/22 Patient ID: 10202420 Test performed: CT/GC /TV assay 9/23/22 Patient ID: 10202450 Test performed: CT/GC/TV assay 9/24/22 Patient ID: 10202532 Test performed: SARS-CoV-2 9/24/22 Patient ID: 10202512 Test performed: CT/GC/TV assay 9/24/22 Patient ID: 10202529 Test performed: CT /GC/TV assay 11/2/22 Patient ID: 10204797 Test performed: CT/GC/TV assay 11/2 /22 Patient ID: 10204797 Test performed: Vaginal Panel 11/2/22 Patient ID: 10204860 Test performed: Vaginal Panel 11/3/22 Patient ID: 10204919 Test performed: CT/GC/TV assay 11/3/22 Patient ID: 10204905 Test performed: CT/GC /TV assay 11/3/22 Patient ID: 10204860 Test performed: Vaginal Panel 11/3/22 Patient ID: 10204893 Test performed: Vaginal Panel 11/3/22 Patient ID: 10204888 Test performed: Vaginal Panel 11/3/22 Patient ID: 10204905 Test performed: Vaginal Panel 11/3/22 Patient ID: 10204919 Test performed: Vaginal Panel 11/4/22 Patient ID: 10204948 Test performed: CT/GC/TV assay 11/4/22 Patient ID: 10204946 Test performed: CT/GC/TV assay 11/4/22 Patient ID: 10204940 Test performed: CT/GC /TV assay 11/4/22 Patient ID: 10204993 Test performed: CT/GC/TV assay 11/4/22 Patient ID: 10204994 Test performed: CT/GC/TV assay 11/4/22 Patient ID: 10204958 Test performed: CT/GC/TV assay 11/4/22 Patient ID: 10204948 Test performed: Vaginal Panel 11/4/22 Patient ID: 10204940 Test performed: Vaginal Panel 11/4/22 Patient ID: 10204993 Test performed: Vaginal Panel 11/4/22 Patient ID: 10204958 Test performed: Vaginal Panel 11/4/22 Patient ID: 10204994 Test performed: Vaginal Panel 11/5/22 Patient ID: 10205020 Test performed: CT/GC/TV assay 11/5/22 Patient ID: 10205019 Test performed: Vaginal Panel 11/7/22 Patient ID: 10205154 Test performed: CT/GC/TV assay 11/8/22 Patient ID: 10205170 Test performed: CT/GC /TV assay 11/8/22 Patient ID: 10205159 Test performed: CT/GC/TV assay 11/8/22 Patient ID: 10205235 Test performed: CT/GC/TV assay 11/8/22 Patient ID: 10205139 Test performed: CT/GC/TV assay 11/8/22 Patient ID: 10205175 Test performed: CT /GC/TV assay 11/8/22 Patient ID: 10205145 Test performed: CT/GC/TV assay 11/8 /22 Patient ID: 10205176 Test performed: CT/GC/TV assay 11/8/22 Patient ID: 10205175 Test performed: Vaginal Panel 11/8/22 Patient ID: 10205170 Test performed: Vaginal Panel 11/8/22 Patient ID: 10205159 Test performed: Vaginal Panel 11/8/22 Patient ID: 10205139 Test performed: Vaginal Panel 11/8/22 Patient ID: 10205235 Test performed: Vaginal Panel 11/8/22 Patient ID: 10205176 Test performed: Vaginal Panel 11/8/22 Patient ID: 10205145 Test performed: Vaginal Panel 11/9/22 Patient ID: 10205242 Test performed: CT/GC/TV assay 11/9/22 Patient ID: 10205251 Test performed: CT/GC/TV assay 11/9/22 Patient ID: 10205283 Test performed: CT/GC/TV assay 11/9/22 Patient ID: 10205283 Test performed: Vaginal Panel 11/9/22 Patient ID: 10205242 Test performed: Vaginal Panel 11/9/22 Patient ID: 10205251 Test performed: Vaginal Panel 11/11/22 Patient ID: 10205489 Test performed: Vaginal Panel 11/11/22 Patient ID: 10205490 Test performed: Vaginal Panel 11/11/22 Patient ID: 10205488 Test performed: Vaginal Panel 11/11/22 Patient ID: 10205492 Test performed: Vaginal Panel 11/11/22 Patient ID: 10205453 Test performed: Vaginal Panel 11/11/22 Patient ID: 10205491 Test performed: Vaginal Panel 11/11/22 Patient ID: 10205514 Test performed: Vaginal Panel 11/11/22 Patient ID: 10205536 Test performed: Vaginal Panel 11/15/22 Patient ID: 10205680 Test performed: Vaginal Panel 11/15/22 Patient ID: 10205695 Test performed: Vaginal Panel 11/15/22 Patient ID: 10205716 Test performed: Vaginal Panel 11/16/22 Patient ID: 10205781 Test performed: Vaginal Panel 11/16/22 Patient ID: 10205831 Test performed: Vaginal Panel 4. An interview with the laboratory manager on 11/20/22 at 11:50 am in the office confirmed the above findings. Key: QCP=Quality Control Plan CT=Chlamydia trachomatis GC=Neisseria gonorrhoeae TV=Trichomonas vaginalis
D5785	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer requirements for storage of reagents for the IL (Instrumentation Laboratory) ACL Elite analyzer, review of laboratory's temperature logs for April to October of 2022, review of laboratory's corrective action documentation for 2022 and staff interview, it was determined the laboratory failed to document corrective action for out-of-range room temperature for 99 of 214 days reviewed. Findings included: 1. Surveyor's observations on 11/21/2022 at 1300 hours in the laboratory reveled the laboratory stored the following IL ACL Elite reagents in the Instrument Room: Wash-R Emulsion Lot: N0128147 Expiration: 2024-01 Wash-R Emulsion Lot: N0329550 Expiration: 2024-03 HemosIL Cleaning agent Lot: N1015780 Expiration: 2022-12 HemosIL Cleaning agent Lot: N0612503 Expiration: 2023-06 2. Review of the manufacturer requirements for storage of the IL ACL Elite reagents revealed the reagent storage temperature was defined as 15-25C (Celsius). 3. Review of laboratory's temperature logs for April to October of 2022 revealed the temperature for the Instrument Room was out of defined range (18-25C) on the following 99 of 214 days reviewed: Date: Recorded temperature: 05/29/2022 25.1C 06/01/2022 25.3C 06/02/2022 25.5C 06/03/2022 25.1C 06/04/2022 25.1C 06/05 /2022 25.5C 06/08/2022 25.3C 06/10/2022 25.1C 06/11/2022 25.5C 06/13/2022 25.3 C 06/14/2022 25.3C 06/15/2022 25.3C 06/16/2022 25.7C 06/17/2022 25.5C 06/18 /2022 25.1C 06/20/2022 25.1C 06/21/2022 25.1C 06/22/2022 25.1C 06/23/2022 25.7 C 06/24/2022 25.2C 06/25/2022 25.5C 06/28/2022 25.1C 06/29/2022 25.3C 06/30 /2022 25.5C 07/04/2022 25.3C 07/05/2022 25.3C 07/06/2022 25.3C 07/07/2022 25.7 C 07/08/2022 25.9C 07/09/2022 25.5C 07/11/2022 25.7C 07/12/2022 25.7C 07/13 /2022 25.7C 07/14/2022 25.5C 07/15/2022 25.5C 07/18/2022 25.5C 07/19/2022 25.7 C 07/20/2022 25.7C 07/21/2022 26.7C 07/22/2022 26.1C 07/23/2022 25.7C 07/24 /2022 25.9C 07/25/2022 26.3C 07/26/2022 26.3C 07/27/2022 25.7C 07/28/2022 25.9 C 07/29/2022 26.3C 07/30/2022 26.3C 07/31/2022 25.9C 08/01/2022 25.5C 08/02 /2022 25.5C 08/03/2022 25.5C 08/08/2022 25.7C 08/09/2022 25.3C 08/15/2022 25.3 C 08/16/2022 25.5C 08/17/2022 25.3C 08/19/2022 25.5C 08/20/2022 25.3C 08/21 /2022 25.7C 08/22/2022 25.5C 08/24/2022 26.1C 08/27/2022 25.7C 08/28/2022 26.3 C 08/29/2022 25.7C 08/30/2022 25.1C 08/31/2022 25.1C 09/01/2022 26.3C 09/02 /2022 26.1C 09/03/2022 26.3C 09/04/2022 25.5C 09/05/2022 25.2C 09/06/2022 25.7 C 09/07/2022 26.7C 09/08/2022 27.1C 09/09/2022 27.6C 09/11/2022 27.6C 09/12 /2022 27.1C 09/13/2022 26.1C 09/14/2022 26.1C 09/18/2022 27.1C 09/19/2022 26.6 C 09/20/2022 25.7C 09/21/2022 26.1C 09/23/2022 28.4C 09/24/2022 25.9C 09/25 /2022 25.7C 09/26/2022 26.5C 09/27/2022 25.3C 09/28/2022 25.1C 10/02/2022 25.5 C 10/06/2022 25.3C 10/08/2022 25.6C 10/09/2022 26.6C 10/10/2022 25.1C 10/17 /2022 26.6C 10/23/2022 25.5C 10/24/2022 25.9C 10/25/2022 25.9C 4. Review of laboratory's corrective action documentation for 2022 revealed there was no documentation of corrective action for out-of-range temperatures for the Instrument Room for any of the above 99 dates. 5. In an interview on 11/21/2022 at 1330 hours in the office, the laboratory's General Supervisor number 1 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory's 2021 and 2022 calibration verification records, review of laboratory's 2022 instrument maintenance records and instrument manuals, review of laboratory's 2022 temperature and corrective action records and staff interview it was determined the laboratory's Quality Assurance (QA) failed to identify and address issues with calibration verification intervals, instrument maintenance intervals and out-of-range temperature corrective action documentation. Refer to D5429, D5439 and D5785.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory's staff training and competency assessment records, review of random patient results from September of 2022 and staff interview it was determined the Laboratory Director failed to ensure staff training completion and competency was documented prior to patient testing for Testing Person number 5 (TP5), 1 of 6 testing personnel employed by the facility. Findings included: 1. Review of laboratory's staff records revealed TP5 was hired in March of 2022. 2. Review of TP5's training documents revealed ID NOW COVID-19 and DxH900 Basic Operator hematology analyzer training documents were signed by TP5 but did ot have trainer designation/signature and/or training completion date. 3. Review of TP5's initial competency assessment revealed the initial competency assessment was documented on 09/20/2022. 4. Review of random patient results from September of 2022 revealed the following patients were tested by TP5 prior to initial competency assessment and documentation of training completion: Date: 09/05/2022 Patient: 10201360 Test: Complete Blood Count Date: 09/07/2022 Patient: 10201462 Test: COVID Date: 09/16 /2022 Patient: 10202083 Test: COVID 5. In an interview on 11/21/2022 at 1040 hours in the office, the laboratory's General Supervisor number 1 (as defined on submitted Form 209), after review of the data, confirmed the findings.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the

	laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs for 2022, review of laboratory's corrective action logs for the same interval, review of laboratory's reagent storage requirements and staff interview it was determined the Technical Consultant failed to ensure corrective actions were documented for out-of-range temperatures. Refer to D5785.