Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0659755	(X3) Date Survey Completed 01/26/2023
Name of Provider or Supplier Preferred Hospital Leasing Hemphill Inc	**Street Address, City, State** 2301 Worth Street, Hemphill, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based upon review of the laboratory's list of non-waived tests, proficiency testing policy, proficiency testing records patient test records and interview of facility personnel, the laboratory failed to enroll in a proficiency testing program for the Bacteriology, Parasitology and Virology pathogens tested using the Biofire GI panel. The laboratory tested 62 patient specimens (for 22 targets each) between January 21, 2022 and January 25, 2023. The findings included: 1. Review of the laboratory's list of non-waived tests provided during the onsite inspection found the laboratory tested patient specimens using the Biofire GI panel which includes the following pathogens: Adenovirus F40/41 Astrovirus Clostridium Dificile Toxin A\B Campylobacter Cryptosporidium Cyclospora cayetanensis Entamoeba histolytica Enteroaggregative E. coli Enteropathogenic E coli Enterotoxigenic E coli Giardia lamblia Norovirus G I /II Plesiomonas shigelloides Rotavirus A Shigella/ Enteroinvasive E. coli Salmonella Sapovirus Shiga-like Toxin E. coli Vibrio (V. parahaemoliticus/ V. vulnificus/ V. cholera) Vibrio Cholerae Yersinia enterocolitica 2. Review of the laboratory's own written policy 44-06 titled Proficiency Testing (10/14/19) found on page one under Procedure: "The Laboratory shall participate in a proficiency testing program covering all Laboratory specialties and subspecialties for which the Laboratory is

	approved to perform tests." 3. Review of proficiency testing records found no evidence of the laboratory participating in a proficiency testing program in 2022 for the GI panel. 4. Review of patient test records provided found the laboratory tested 62 patient specimens (for 22 targets each) between January 21, 2022 and January 25, 2023. 5. During interview of the General Supervisor listed on the CMS report 209 Laboratory Personnel Report conducted January 25, 2023 at 11:33 AM, he confirmed that he had not enrolled in a proficiency testing program for the GI panel until the enrollment period for 2023.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on a review of laboratory documents, laboratory policy, the Centers for Medicare and Medicaid Services (CMS) 116 application, and confirmed in an interview, the laboratory failed to retain the supporting data utilized to conduct the risk assessment (RA) portion of the laboratory's individualized quality control plan (IQCP) used to reduce the quality control (QC) frequency from every day of patient testing for two of two moderate complexity tests with and IQCP reviewed in 2022. The findings include: 1. Review of the laboratory IQCP binder included the following two moderate complexity procedures in use by the laboratory with the following quality control plan (QCP) obtained from laboratory policy "Alere Triage Cardiac Panel" and "Sure-Vie Serum/Urine hCG", respectively: Alere Triage Cardiac Panel: External Quality Control: "Level 1 and 2 liquid controls are tested with new Box/lot of test materials or every 30 days, whichever comes first." Sure-Vue Serum hCG: External Control: "Serum Controls - Serum controls are ran with every new box opened or every 30 days which ever comes first. Note: Per CMS guidelines a risk assessment has been performed and Sabine County Hospital Laboratory has determined for this moderate complex test, and IQCP was developed. For further explanation refer to the IQCP to the IQCP information." 2. Review of the laboratory's IQCP risk assessment activities used in the determination of potential failures and errors for the testing process, did not include the supporting laboratory data used in the risk assessment evaluation. Surveyor queried for the supporting laboratory data used in the risk assessment on 1/26/2023 at 09:30 hours, in the conference room, and none was provided. 3. Review of laboratory test volumes, provided by the general supervisor (GS), listed the following annual test volumes for 2022: hCG Serum: 145 Alere Triage Cardiac Panel: 28 4. In an interview, on 1/29/2023 at 09:38 hours, in the conference room, testing person (TP) 1 confirmed that the laboratory failed to retain the supporting laboratory data used for the RA evaluation portion of the laboratory's IQCP.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based upon review of the laboratory's list of non-waived tests, proficiency testing policy, proficiency testing records patient test records and interview of facility personnel, the laboratory failed to enroll in a proficiency testing program or have a means of verifying the accuracy of results for the Chemistry analyte Ammonia. The laboratory tested 44 patient specimens for Ammonia between May 6, 2021 and January 25, 2023. The findings included: 1. Review of the laboratory's list of non-waived tests provided during the onsite inspection found the laboratory tested patient specimens for Ammonia using the Ortho Vitros 5600 Chemistry analyzer 2. Review of the laboratory's own written policy 44-06 titled Proficiency Testing (10/14/19) found on page one under Procedure: "The Laboratory shall participate in a proficiency testing program covering all Laboratory specialties and subspecialties for which the Laboratory is approved to perform tests." 3. Review of proficiency testing records found no evidence of the laboratory participating in a proficiency testing program in 2021 or 2022 for Ammonia and they did not have another means to verify the accuracy of results. 4. Review of patient test records provided found the laboratory tested 44 patient specimens for Ammonia between May 6, 2021 and January 25, 2023. 5. During interview of the General Supervisor listed on the CMS report 209 Laboratory Personnel Report conducted January 25, 2023 at 11:33 AM, he confirmed that he had not enrolled in a proficiency testing program for Ammonia until January 25, 2023.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based upon review of the laboratory's verification study for the Cell Dyn Ruby hematology analyzer, the laboratory's own written policy, patient test records and interview of facility personnel, the laboratory failed to verify the reference ranges for the parameters of the Complete Blood Count (CBC) using the Cell Dyn Ruby were appropriate for the patient population before testing patient specimens. The laboratory reported an annual volume of 32,200 Hematology tests. The findings included: 1. Review of the laboratory's verification study found no verification of reference ranges for the Cell dyn Ruby (Serial Number 7121fBG) installed in October 2019. 2. Review of the laboratory's own written procedure titled Cell-Dyn Ruby Operation Guide (Effective 1/2020) found on page 8 under the Heading Reporting Results: Reference ranges for the various tests and age groups can be found in the LIS. Reference Range: WBC 4.8-10.8 mm3 RBC (M) 4.7-6.1 mil (F) 4.2-5.4 Hgb (M) 14-18 g/dl (F) 12-16 g /dl Hct (M) 42-52% (F) 37-47% MCV (M) 80-94 fl (F) 81-99 fl MCH 27-31 pg MCHC 32-36 g/dl RDW 11.5-15.5 % Plt 130-400 x10^3 MPV 7.4-10.4 fl Gran % 43-65% Lymph% 20.5-45.5% Mono% 5.5-11.7% Eos % 0.0-0.2% Baso% 0.0-0.1% 3. Review of final patient reports printed from the LIS for male and female patients found the following reference ranges: Male: WBC 4.0-11.0 x10^3 RBC 4.5-6.1 x10^6 Hgb 14.0 - 17.0 g/dL Hct 42.0 -52.0 % MCV 80-94 fL MCH 27.0 - 31.0 pg MCHC

	33.0 -37.0 g/dL RDW 11.5-14.5 % Plt 150 - 400 x10^3 MPV 7.4 - 11.5 fL Gran % 45 - 70% Lymph% 15.0 - 60.0% Mono% 2.0 -10.0% Eos % 0.0 - 7.0% Baso% 0.0 -2.0% Female: WBC 4.0-11.0 x10^3 RBC 3.5-6.0 x10^6 Hgb 12.0 - 16.0 g/dL Hct 36.0 - 48.0 % MCV 81 - 99 fL MCH 27.0 - 31.0 pg MCHC 33.0 -37.0 g/dL RDW 11.5-14.5 % Plt 150 - 400 x10^3 MPV 7.4 - 11.5 fL Gran % 45 - 70% Lymph% 15.0 - 60.0% Mono% 2.0 -10.0% Eos % 0.0 - 7.0% Baso% 0.0 -2.0% 4. During interview of the general supervisor conducted January 26, 2023 at 11:01 AM he stated that the reference ranges in the LIS were from the previous hematology analyzer and he did not change them.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory test menu, quality control (QC) documents, patient reports, and confirmed in interview, the laboratory failed to perform quality control every day of patient testing for the Alere Triage Tox Drug Screen, 94600 for 30 of 30 patients reviewed in May and October of 2022. The findings include: 1. Review of the laboratory test menu included moderate complexity "Triage Tox Drug Screen, 94600" test performed on the triage meter. 2. Review of laboratory policies did not include a policy approved by the laboratory director for the "Triage Tox Drug Screen". Surveyor queried the general supervisor (GS) for the quality control policy for the test and was informed by the GS that external liquid control was run every 30 days, and with every new lot. Surveyor queried for the laboratory's individual quality control plan (IQCP) to support the reduction in QC frequency from every day of patient testing to every 30 days, and with every new lot, but none was provided. 3. Review of the laboratory QC documents for May and October 2022, and patient testing records, had the following 30 patients tested with the Triage Tox Drug Screen, 94600 on days where QC was not performed. May 2022: 18 patients 5/2/2022: 2205020051 2205020082 5/3/2022: 2205030054 5/5/2022: 2205070017 5/11/2022: 2205110060 2205110069 5/13/2022: 2205130052 2205130073 5/14/2022: 2205140012 5/20/2022: 2205200040 5/21/2022: 2205210011 2205210027 5/23/2022: 2205230041 2205230053 5/25/2022: 2205250057 5/26/2022: 2205260008 5/28/2022: 2205280002 5/29/2022: 2205290004 October 2022: 12 patients 10/2/2022: 2210020058 10/05/2022: 2210050010 10/8/2022: 2210080006 10/12/2022: 2210120075 10/13/2022: 2210130019 2210130082 10/15/2022: 2210150005 10/16 /2022: 2210160022 10/19/2022: 2210190078 10/20/2022: 2210200008 10/29/2022: 2210290005 2210290024 3. In an interview on 1/26/2023 at 09:35 hours, in the conference room, testing person (TP) 1 confirmed that the laboratory did not perform an external liquid QC every day of patient testing for the moderate complexity test, Triage Tox Drug Screen, 94600.
D5545	HEMATOLOGY

	CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Review of APTT (Activated Partial Thromboplastin Time)and Prothrombin time quality control records, patient test records, and interview of facility personnel found that the laboratory tested one patient for Prothrombin Time in November, 2022 without testing at least two levels of quality control material at least every 8 hours when performing prothrombin Time testing using the ACL elite coagulation analyzer. The findings included: 1. A review of the laboratory's quality control records for November 2022 found that the laboratory failed to test at least 2 levels of quality control material every 8 hours for APTT and Prothrombin Time as follows: November 1, 2022 between 09:17 and November 2, 2022 08:17- 23 hours November 2, 2022 between 15:06 and November 3, 2022 08:27 - 17 hours 21 minutes November 3, 2022 between 08:27 and 17:08 8 hours 41 minutes November 3, 2022 between 17:08 and November 4, 2022 07:31 - 14 hours 23 minutes November 4, 2022 between 15:23 and November 6, 2022 18:09 - 50 hours 46 minutes November 6, 2022 between 18:09 and November 7, 2022 10:26 - 15 hours 49 minutes November 7, 2022 10:26 and November 8, 2022 09:11 - 23 hours 43 minutes November 8, 2022 09:11 and November 9, 2022 07:17 - 22 hours 6 minutes November 9, 2022 07:17 and November 10, 2022 08:30 - 25 hours 13 minutes November 10, 2022 08:30 and November 11, 2022 06:34 - 22 hours 4 minutes November 11, 2022 13:53 and November 13, 2022 02:41 - 36 hours 48 minutes November 13, 2022 16:02 and November 14, 2022 - 08:03 - 16 hours 1 minute November 14, 2022 - 08:03 and November 15, 2022 07:17 - 23 hours 14 minutes November 15,2022 17:53 and November 16, 2022 07:34 - 13 hours 40 minutes November 16, 2022 16:01 and November 17, 2022 08:51 - 15 hours 52 minutes November 17, 2022 20:12 and November 18, 2022 07:43 - 11 hours 31 minutes November 18, 2022 07:43 and November 19, 2022 08:43 - 25 hours November 19, 2022 08:43 and November 20, 2022 07:26 - 22 hours 43 minutes November 20, 2022 07:26 and November 21, 2022 08:04 - 24 hours 38 minutes November 21, 2022 15:39 and November 22, 2022 08:04 - 17 hours 25 minutes November 22, 2022 15:45 and November 23, 2022 07:58 - 16 hours 3 minutes November 23, 2022 07:58 and November 24, 2022 01:13 - 19 hours 15 minutes November 24, 2022 01:13 and November 25, 2022 08:31 - 31 hours 18 minutes November 25, 2022 08:31 and November 28, 2022 08:48 - 72 hours 18 minutes November 28, 2022 18:14 and November 29, 2022 08:14 - 16 hours November 29, 2022 15:45 and November 30, 2022 08:03 -16 hours 18 minutes 2. Review of patient test records found that the laboratory tested one patient specimens for APTT and Prothrombin Time on November 27, 2022 without testing quality control materials. Patient 50896 was tested for APTT and Prothrombin Time at 17:54, with the last quality control testing done 55 hours and 29 minutes before on November 25, 2022 at 18:14. 3. Interview of testing person one on the CMS Report 209 Laboratory Personnel Report confirmed during interview conducted January 26, 2023 at 3:18 PM that testing personnel only tested quality control materials at least once every 8 hours when patient specimens were tested, but they missed this one.
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 laboratory documents and confirmed in interview, the laboratory failed to perform a twice annual comparison of test results for three of three analytes performed on the Triage and the Vitros 5600 chemistry analyzer in 2022. The findings include: 1. Review of the laboratory test menu for 2022 had the following tests being performed on both the Triage and the Vitros 5600 chemistry analyzer: CKMB Troponin I BNP Surveyor queried for the twice-annual evaluation of test results, and none was provided. 2. Review of the laboratory-provided annual test volume had the following test totals for each analyzer: Triage: CKMB - 26 Troponin I - 28 BNP - 61 Vitros 5600 Chemistry Analyzer: CKMB - 8 Troponin I - 48 BNP - 647 3. In an interview on 1/26/2023 at 15:48 hours, in the conference room, testing person 1 confirmed that the laboratory had not performed a twice-annual comparison of test results for CKMB, Troponin I, and BNP between the two chemistry analyzers.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, quality control (QC) documents, patient results, and confirmed in an interview the laboratory failed to document remedial action for 59 of 59 patients' results to the last acceptable QC when QC results were outside of the laboratory's established criteria for acceptability for lactate dehydrogenase (LDH) testing on the Vitros 5600 chemistry analyzer reviewed in December 2022. The findings include: 1. Review of the laboratory policy titled "Quality control Policy" stated the following: "Westgard rules will be used to establish limits for accepting control runs for Chemistry, Hematology, Coagulation and Urinalysis. Chemistry: A minimum of three levels of controls will be used to validate tests daily." Surveyor queried as to the type of QC material used in daily QC, as it was not stated in the control policy, the general supervisor stated they used Bio-Rad QC. A review of the laboratory policy titled "Westgard Rules For Control Policy", subsection "Policy" had the following statement and rules criteria for QC acceptability: "Patient values must not be reported until controls have been run and are within the established limits. These limits are determined using the Westgard rules. Further, the Westgard rules are used to aid in detecting instrument, reagent, and /or control problems. Rule Definition 1-3S One QC result is outside the x+3 SD limit. Patient Data: Not acceptable 2-3SA Two consecutive results exceed the same X+ 2SD

or X-2 SD limit. Patient Data: Not acceptable 2-2SW Two consecutive results exceed the same X+ 2SD or X-2 SD limit within the same level of QC. Patient Data: Not acceptable R4SA one QC level result exceeds X + 2 SD and another exceeds x-2 SD within the same run (range or difference between two exceeds 4 SD). Patient Data: Not acceptable 4-ISW Four consecutive results exceed the same x+1 SD limit within the same QC level. Patient Data: Not acceptable 4-ISA 4 consecutive results exceed the same x+1SD or x-1 SD limit across multiple levels of QC. Patient Data: Not acceptable 10-MW 10 consecutive results fall on the same side of the mean within one level of QC. Patient Data: Shift 10-MA 10 consecutive results fall on the same side of the mean across multiple levels of QC. Patient Data: Shift 7-TR Seven consecutive results moving in the same direction, beginning to indicate a trend within one level of QC." 2. In a review of the QC records from December 2022 surveyor noticed the use of performance verifiers (PV's) for out-of-control Bio-Rad QC issues. The general supervisor stated that they use PV's when Bio-Rad QC is out of limits. Surveyor queried for documentation, in policy, for said QC practices and none was provided. Review of QC records and patient test results had the following LDH QC failures with the Bio-Rad control, and the 59 patients tested since the last acceptable QC: 12/2/2022 Analyte QC - Result - Expected Values LDH Level 3 (L3) - 441.4 - 336.0-402.0 Corrective action: Run LDHI with performance verifiers 5 patients ran since the last acceptable QC on 12/1/2022 2212010002 2212010018 2212010085 2212010091 2212010092 12/3/2022 Analyte QC - Result - Expected Values LDHI L3 - 410.7 - 366.0-402.0 Corrective action: Run LDHI with performance verifiers 4 patients ran since the last acceptable QC on 12/2/2022 2212020042 2212020049 2212020054 2212020099 12/4/2022 Analyte QC - Result - Expected Values LDHI L3 - 409.5 - 366.0 - 402.0 Corrective action: Ran LDHI with performance verifiers 1 patient ran since the last acceptable QC on 12/03/2022 2212030001 12/5/2022 Analyte QC - Result - Expected Values LDH L3 - 407.5 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 2 patients ran since the last acceptable QC on 12/04/2022 2212040005 2212040015 12/6/2022 Analyte QC - Result - Expected Values LDH L3 - 412.2 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 1 patient ran since the last acceptable QC on 12/05/2022 2212050106 12/7/2022 Analyte QC - Result - Expected Values LDH L3 - 417.9 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 2 patients ran since the last acceptable QC on 12/06/2022 2212060048 2212060054 12/8/2022 Analyte QC - Result - Expected Values LDH L3 - 411.9 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 8 patients ran since the last acceptable QC on 12/07/2022 2212070008 2212070012 2212070041 2212070059 2212070062 2212070071 2212070073 2212070077 12/10/2022 Analyte QC - Result - Expected Values LDH L3 - 415.9 - 366.0 - 402.0 Corrective action: Ran LDHI with performance verifiers 1 patient ran since the last acceptable QC on 12/09/2022 2212090042 12/11/2022 Analyte QC - Result - Expected Values LDHI L3 - 408.8 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 4 patients ran since the last acceptable QC on 12/10/2022 2212100002 2212100008 2212100014 2112100026 12/13/2022 Analyte QC - Result - Expected Values LDHI L3 - 407.8 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 8 patients ran since the last acceptable QC on 12/12/2022 2212120001 2212120003 2212120013 2212120020 2212120065 2212120075 2212120085 2212120088 12/16/2022 Analyte QC - Result - Expected Values LDHI L3 - 409.2 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 2 patients ran since the last acceptable QC on 12/15/2022 2212150043 2212150064 12/17/2022 Analyte QC - Result - Expected Values LDHI L3 - 416.5 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 9 patients ran since the last acceptable QC on 12/16/2022 2212160005 2212160025 2212160089 2212160102 2212160126 2212160135 2212160144 2212160150

	2212160163 12/18/2022 Analyte QC - Result - Expected Values LDHI L3 - 414.3 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 1 patient ran since the last acceptable QC on 12/17/2022 2212170001 12/19/2022 Analyte QC - Result - Expected Values LDHI L3 - 420.5 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 1 patient ran since the last acceptable QC on 12/18 /2022 2212180008 12/22/2022 Analyte QC - Result - Expected Values LDHI L3 - 415.7 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 5 patients ran since the last acceptable QC on 12/21/2022 2212210004 2212210027 2212210042 2212210076 2212210085 12/31/2022 Analyte QC - Result - Expected Values LDHI L2 - 188.6 - 167.3-186.7 Corrective action: Ran LDHI with performance verifiers Analyte QC - Result - Expected Values LDHI L3 - 413.0 - 366.0-402.0 Corrective action: Ran LDHI with performance verifiers 5 patients ran since the last acceptable QC on 12/30/2022 2212300010 2212300038 2212300043 2212300065 2212300077 Surveyor queried for documentation that patients were remediated to the last acceptable QC for when QC was out of laboratory-established limits, and none was provided. 3. In an interview on 1/26/2022 at 14:06, in the conference room, the GS confirmed that there was no documented patient remedial action for LDH quality control issues on the Vitros 5600 Chemistry analyzer for the month of December 2022.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based upon review of laboratory policies and procedures, manufacturer's specifications, patient test records and interview of facility personnel found that the laboratory director failed to ensure that verification of reference ranges had been conducted prior to testing patient specimens using the Cell-dyn Ruby hematology analyzer. (See D5421)
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Review of the CMS 155 Individual Laboratory Profile, Proficiency testing records, patient test records and interview of facility personnel found that the laboratory

	director failed to ensure that the laboratory was enrolled and participated in an approved proficiency testing program for nonwaived testing in Bacteriology, Virology, Parasitology and Chemistry. (see D 2000 and D 5217)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Review of quality control records and interview of facility personnel found that the laboratory director failed to ensure that the quality control program was established and maintained for hematology . (See D5445)
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of laboratory competency assessments, the laboratory provided Centers For Medicare & Medicaid Services (CMS) laboratory personnel report 209, and confirmed in interview, the technical consultant failed to evaluate the competency of five of five testing personnel performing moderate complexity testing in 2022. The findings include: 1. Review of the laboratory competency assessments for 2022, and the CMS laboratory personnel report 209, had the following testing personnel (TP) evaluated for competency by personnel who could not be qualified as a technical consultant under 42 CFR 493.1411: TP1 evaluated by the general supervisor (GS) TP2 evaluated by TP1 TP3 evaluated by TP1 TP4 evaluated by TP1 TP5 evaluated by GS 2. In an interview on 1/25/2023 at 11:45 hours, in the conference room, the general supervisor confirmed that personnel competency assessment for moderate compacity testing had not been performed by personnel who could be qualified as a technical consultant.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on a review of laboratory competency assessments, the laboratory provided Centers For Medicare & Medicaid Services (CMS) laboratory personnel report 209, and confirmed in an interview, the technical supervisor failed to evaluate the competency for five of five testing personnel performing high complexity testing in 2022. The findings include: 1. Review of the laboratory competency assessments for 2022, and the CMS laboratory personnel report 209, had the following testing personnel (TP) evaluated for competency by personnel who could not be qualified as a technical supervisor under 42 CFR 493.1449 paragraphs (b) or (q): TP1 evaluated by the general supervisor (GS) TP2 evaluated by TP1 TP3 evaluated by TP1 TP4 evaluated by TP1 TP5 evaluated by GS 2. In an interview on 1/25/2023 at 11:45 hours, in the conference room, the general supervisor confirmed that personnel competency assessment for high complexity testing had not been performed by personnel who could be qualified as a technical supervisor.