Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2128678	12/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Altru Diagnostics Inc	8566 Katy Freeway Suite 121, Houston, 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	The laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems 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. 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.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on the review of API proficiency testing records for 2022 and confirmed in an interview found the laboratory failed to have documentation of evaluating results returned as 'not graded' by the proficiency testing program for two of three hematology /coagulation events. The findings were: 1. Review of API Proficiency Testing Performance Evaluation revealed "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes." 2. A review of the laboratory's API proficiency testing in 2022 revealed the laboratory failed to have documentation of evaluating results returned as 'not graded' by the proficiency testing program for two of three hematology/coagulation events.

	2022 Hematology/Coagulation 2nd event Educational Blood Cell Identification Analyte/Method Basophil (DIF)(%) Sample: DIF-02 Reported Result 0 Expected result 0-1 Analyte/Method Eosinophil (DIF)(%) Sample: DIF-02 Reported Result 9 Expected result 1-14 Analyte/Method Lymphocyte (DIF)(%) Sample: DIF-02 Reported Result 29 Expected result 11-42 Analyte/Method Lymphocyte, reactive (DIF)(%) Sample: DIF-02 Reported Result 1 Expected result 0-8 Analyte/Method Monocyte (DIF)(%) Sample: DIF-02 Reported Result 7 Expected result 0-16 Analyte /Method Neutrophil, seg or band (DIF)(%) Sample: DIF-02 Reported Result 54 Expected result 41-71 Analyte/Method Platelet estimate (DIF) Sample: DIF-02 Reported Result Adequate/Normal Expected result Adequate/Normal Analyte/Method Blood Cell ID (Educational) Sample: ECI-06 Reported Result Sickle Cell (drepanocyte) Expected result Sickle Cell (drepanocyte) Sample: ECI-07 Reported Result Target cell (codocyte) Expected result Target cell (codocyte) Sample: ECI-08 Reported Result Neutrophil, segmented Expected result Neutrophil, segmented Sample: ECI-09 Reported Result Monocyte Expected result Platelet(s), giant Sample: ECI-10 Reported Result Nucleated red blood cell Expected result Nucleated red blood cell 2022 Hematology/Coagulation 3rd event Educational Blood Cell Identification Analyte/Method Basophil (DIF)(%) Sample: DIF-03 Reported Result 1 Expected result 0-2 Analyte/Method Lymphocyte (DIF)(%) Sample: DIF-03 Reported Result 20 Expected result 11-25 Analyte/Method Monocyte (DIF)(%) Sample: DIF-03 Reported Result 4 Expected result 0-9 Analyte/Method Neutrophil, band (DIF)(%) Sample: DIF-03 Reported Result 1 Expected result 0-2 Analyte/Method Neutrophil, segmented (DIF)(%) Sample: DIF-03 Reported Result 74 Expected result 70-83 Analyte/Method Platelet estimate (DIF) Sample: DIF-03 Reported Result Adequate/Normal Expected result Adequate/Normal Analyte/Method Blood Cell ID (Educational) Sample: ECI-11 Reported Result Neutrophil, hypersegmented Expected result Neutrophil, hypersegmented Sample: ECI-12 Reported Result Polychromatophilic RBC Expected result Polychromatophilic RBC Sample: ECI-13 Reported Result Macrocytic red blood cell Expected result Macrocytic red blood cell Sample: ECI-14 Reported Result Lymphocyte, normal Expected result Lymphocyte, normal Sample: ECI-15 Reported Result Monocyte Expected result Monocyte 3. An interview with the technical consultant (TC) on 12/21/22 at 1:05 pm in the TC office confirmed the above findings. Key: API=American Proficiency Institute RBC=Red Blood Cell
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of API proficiency testing records for 2022, the laboratory's alternative proficiency testing records for 2022, the laboratory's records, and confirmed in an interview found the laboratory failed to have documentation of performing twice annual accuracy assessments for 2022 for two non-regulated analytes on two of four chemistry analyzers. a. C-peptide on Beckman Coulter Unicel DxI 600 chemistry analyzer b. IGFBP-3 on Siemens Immulite 2000 XPi chemistry analyzer The findings were: a. C-peptide 1. Review of the laboratory's records revealed non-regulated analyte C-peptide was validated on 12/21/2021. 2. Review of the API proficiency testing records revealed the laboratory failed to have documentation of C-peptide to perform at least twice annually with API agency on Beckman Coulter Unicel DxI 600 (SN:901724). b. IGFBP-3 3. Review of the

	laboratory's alternative proficiency testing records for 2022 revealed the laboratory failed to verify one of two accuracy assessments for non-regulated analyte, IGFBP-3, on Siemens Immulite 2000 XPi (SN: H2177). 4. An interview with the technical consultant (TC) on 12/20/22 at 3:10 pm in the transitional room confirmed the above findings. Key: API=American Proficiency Institute IGFBP-3=Insulin-like growth factor binding protein 3
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 surveyor's observation, review of laboratory's sample transport and courier delivery records, review of laboratory's sample stability studies, review of manufacturer's instructions for use for laboratory's test reagents/kits, review of laboratory's patient test records and staff interview it was determined the laboratory failed to identify, monitor, evaluate and correct problems in overall quality of the pre-analytic systems. Findings included: 1. The laboratory failed to follow manufacturer's sample stability requirements for total Prostate Specific Antigen (PSA) and total Thyroxine (T4). Refer to D5311A. 2. The laboratory failed to follow manufacturer's sample stability and shipment requirements for Vitamin B12. Refer to D5311B. 3. The laboratory failed to ensure specimen shipment temperature specifications were followed/maintained as per policy and specimen acceptability was documented at receipt for courier deliveries. Refer to D5311C. 4. The laboratory failed to establish 2 to 8C specimen stability timeframe for Valproic Acid. Refer to D5311D. 5. The laboratory's Quality Assessment failed to identify, assess and correct problems with pre-analytic systems. Refer to D5391. 6. The laboratory's Quality Assessment failed to include review of the effectiveness of corrective actions taken to resolve problems in pre-analytic systems. Refer to D5311A and B.
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: A. Based on review of the laboratory's policies and procedures, review of manufacturer's instructions for use for the Access DXI chemistry reagents, review of random patient test records for December of 2022 and staff interview, it was determined the laboratory failed to follow manufacturer and its own sample stability

requirements for total Prostate Specific Antigen (PSA) and total Thyroxine (T4) for 3 of 42 samples reviewed. Note: This is a repeat deficiency from the survey conducted on 03/26/2021. Findings included: 1. Review of the laboratory's policy "Clinical Sample Processing", Appendix A, revealed the following sample stability requirements: a. PSA: "RT [room temperature] (15-30C): 8 hrs [hours], Ref [refrigerated] (2-8C): 24 hrs, freeze at -20C or colder if the assay will not be completed within 24 hours" b. Total T4: "RT(15-30C): 8 hrs , Ref(2-8C): 24 hrs, freeze at -20C or colder if the assay will not be completed within 24 hours" 2. Review of manufacturer's instructions for use for the Access DXI chemistry reagents revealed: a. Instructions for Use Access Hybritech PSA Prostate-Specific Antigen (A85067 M, May 2020) under specimen Collection and Preparation: "If the serum sample is to be assayed within 24 hours after collection, the specimen should be stored in a refrigerator at 2-8C. Specimens held for longer (up to 5 months) should be frozen at -20C or colder." b. Instructions for Use for the Access Thyroxine (Total T4) (B16992 J, October 2019) under specimen Collection and Preparation: "If the assay will not be completed within eight hours, refrigerate the samples at 2 to 8C. If the assay will not be completed within 24 hours, or for shipment of samples, freeze at -20C or colder." 3. Review of random patient test records for December of 2022 revealed the following 3 of 42 reviewed samples were tested beyond manufacturer's required sample stability: Test: PSA Sample Accession number: 221216BM0211 Collected: 12/15 /2022 at 10:21 Received: 12/16/2022 at 11:56 Time elapsed: 25 hours 35 minutes Test: PSA Sample Accession number: 221217BM0150 Collected: 12/15/2022 at 16: 50 Received: 12/17/2022 at 11:01 Time elapsed: 42 hours 9 minutes Test: T4 Sample Accession number: 221215BM0157 Collected: 12/14/2022 at 10:03 Received: 12/15 /2022 at 11:35 Time elapsed: 25 hours 32 minutes None of the above samples were frozen either during transport or after receipt. 4. In an interview on 12/21/2022 t 1055 hours in the office, the laboratory's Technical Consultant, after review of the data confirmed the findings. B. Based on review of the laboratory's policies and procedures, review of manufacturer's instructions for use for the UniCel DXI 800 chemistry reagents, surveyor's observations and review of laboratory's sample stability studies, review of random patient test records for December of 2022 and staff interview, it was determined the laboratory failed to follow manufacturer's sample stability and shipment requirements for Vitamin B12 for 15 of 97 samples tested on the UniCel DXI 800. Note: This is a repeat deficiency from the survey conducted on 03/26/2021. Findings included: 1. Review of the laboratory's policies and procedures revealed in "Access Vitamin B12" policy (last reviewed on 10/05/2022): "Specimen Information Stability 8 hours at 15-30C 7 days at 2 to 8C (stability study completed on DXI 600 10/5/22)." 2. Review of manufacturer's instructions for use for the UniCel DXI 800 chemistry reagents revealed: "Instructions For Use Access Vitamin B12 Cobalamin (A09094 L, April 2020) ... SPECIMEN COLLECTION AND PREPARATION ... If the assay will not be completed within eight hours, refrigerate the samples at 2 to 8C. If the assay will not be completed within 24 hours, or for shipment of samples, freeze at -20C or colder. Thaw samples only once." 3. Surveyor's observations on 12/20/2022 at 1000 hours in the laboratory revealed a note attached to the DXI 800 chemistry analyzer stating "Vitamin B12 stability 24 hours". In an interview with the Technical Consultant (TC) at the time of surveyor's observations in the laboratory, the TC stated the note was there to remind the staff that Vitamin B12 should be tested on the DXI 600 instrument if samples were older than 24 hours. When questioned, she also stated that the laboratory very rarely received samples frozen, and only for specialized tests. The laboratory was asked to provide a printout of Vitamin B12 testing from the DXI 800 instrument. 4. Review of laboratory's sample stability studies revealed Vitamin B12 stability was extended to 7 days at 2 to 8C on the DXI 600 instrument only. There was no documentation of an

extended stability study at 2 to 8C for Vitamin B12 on the DXI 800 analyzer, or for shipping Vitamin B12 samples at 2 to 8C. 5. Review of random patient test records for December 17 of 2022 and the submitted printout of Vitamin B12 testing from the DXI 800 instrument revealed the following 15 of 97 patients tested on the DXI 800 exceeded manufacturer required 24 hour at 2 to 8C stability: Sample Accession number: 221217BM0025 Collected: 12/16/2022 at 08:45 Tested: 12/17/2022 at 14:21 Elapsed time: 29hrs (hours) 6min (minutes) Sample Accession number: 221217BM0032 Collected: 12/16/2022 at 08:15 Tested: 12/17/2022 at 14:34 Elapsed time: 31hrs 19min Sample Accession number: 221217BM0035 Collected: 12/16/2022 at 08:35 Tested: 12/17/2022 at 14:40 Elapsed time: 31hrs 5min Sample Accession number: 221217BM0036 Collected: 12/16/2022 at 09:00 Tested: 12/17/2022 at 14:44 Elapsed time: 29hrs 44min Sample Accession number: 221217BM0045 Collected: 12 /16/2022 at 09:28 Tested: 12/17/2022 at 16:10 Elapsed time: 30hrs 42min Sample Accession number: 221217BM0047 Collected: 12/16/2022 at 09:22 Tested: 12/17 /2022 at 14:54 Elapsed time:29hrs 32min Sample Accession number: 221217BM0078 Collected: 12/16/2022 at 08:46 Tested: 12/17/2022 at 15:17 Elapsed time: 30hrs 3min Sample Accession number: 221217BM0084 Collected: 12/16/2022 at 09:00 Tested: 12 /17/2022 at 15:25 Elapsed time: 30hrs 25min Sample Accession number: 221217BM0087 Collected: 12/16/2022 at 09:25 Tested: 12/17/2022 at 16:09 Elapsed time: 30hrs 51min Sample Accession number: 221217BM0088 Collected: 12/16/2022 at 09:45 Tested: 12/17/2022 at 15:41 Elapsed time: 29hrs 56min Sample Accession number: 221217BM0120 Collected: 12/16/2022 at 10:00 Tested: 12/17/2022 at 16:25 Elapsed time:30hrs 25min Sample Accession number: 221217BM0134 Collected: 12 /16/2022 at 10:30 Tested: 12/17/2022 at 16:26 Elapsed time: 29hrs 56min Sample Accession number: 221217BM0150 Collected: 12/15/2022 at 16:50 Tested: 12/17 /2022 at 17:25 Elapsed time: 48hrs 35min Sample Accession number: 221217BM0153 Collected: 12/16/2022 at 08:45 Tested: 12/17/2022 at 16:45 Elapsed time: 32hrs Sample Accession number: 221217BM0187 Collected: 12/16/2022 at 11: 00 Tested: 12/17/2022 at 17:09 Elapsed time: 30hrs 9min None of the above samples were shipped frozen. 6. In an interview on 12/21/2022 at 1055 in the transition area, the laboratory's Technical Consultant, after review of the data, confirmed the findings. C. Based on review of laboratory's sample stability studies and policies, review of laboratory's shipping instructions to clients, surveyor's observations of specimen receipt, review of random shipping logs/currier sign-in sheets and staff interview, it was determined the laboratory failed to ensure specimen shipment temperature specifications were followed/maintained as per policy and specimen acceptability was documented at receipt for courier deliveries. Findings included: 1. Review of laboratory's sample stability studies conducted 06/27/2022 and policies revealed the laboratory established the number of ice packs required to maintain shipping temperature at 2 to 8C. Based on the studies the laboratory created and made available "Packaging guidelines for samples sent on ice" instructions to clients. The laboratory established protocols to document number and condition (frozen/melted) of ice packs per each shipping container. 2. Review of the laboratory's shipping instructions to clients revealed: - "Packaging guidelines for samples sent on ice: ...If Temperature outside is 85F or over, preferably use at least 4 large ice packs or at least 8 small ice packs. If Temperature is below 85F preferably use at least 3 large ice packs or at least 6 small ice packs. ...Big foam box (12x10x11); 35 tubes or less; 6 small (6oz or 8oz) ice packs or 3 large (12oz to 16oz) ice packs. U-Line Metallic Insulated Mailer; 10 tubes or less; 6 small (6oz or 8oz) ice packs or 3 large (12oz to 16oz) ice packs." 3. Surveyor's observations on 12/20/2022 at 1040 hours in the laboratory revealed sample packaging did not follow laboratory's "Packaging guidelines for samples sent on ice" to maintain the 2 to 8C shipping temperature. For example: a. A big foam box (12x10x11), shipped from Paducah, Kentucky, contained 8 blood sample tubes with 2

large (16oz) frozen ice packs. b. A U-Line Metallic Insulated Mailer, shipped from Williamson, West Virginia, contained 6 blood sample tubes and 2 urine tubes with 4 large (12oz) frozen ice packs. Note: The environmental temperature outside was 49F. The laboratory did not verify sample's shipment temperature at receipt. 4. Review of random shipping logs for November and December of 2022 revealed the laboratory's clients did not follow laboratory's guidelines for number of ice packs per shipping container/mailer. For example: On 11/11/2022: Tracking number: 588167178597 Number of blood samples: 2 Number of ice packs/condition: 4 frozen Tracking number: 588167172430 Number of blood samples: 1 Number of ice packs/condition: 2 frozen Tracking number: 1Z115E4FY078916015 Number of blood samples: 1 Number of ice packs/condition: 7 frozen Tracking number: 1Z115E4FY077138877 Number of blood samples: 1 Number of ice packs/condition: 5 frozen On 12/15/2022 Tracking number: 588167183942 Number of blood samples: 1 Number of ice packs /condition: 5 frozen Tracking number: 588167194170 Number of blood samples: 1 Number of ice packs/condition: 4 frozen On 12/17/2022 Tracking number: 588167179479 Number of blood samples: 1 Number of ice packs/condition: 4 frozen Tracking number: 982377162141 Number of blood samples: 1 Number of ice packs /condition: 1 frozen Tracking number: 534291003825 Number of blood samples: 5 Number of ice packs/condition: 2 frozen The laboratory did not document the size of the ice packs or container type. The laboratory did not verify samples' temperature at receipt for acceptability. All samples were accepted for testing. 5. Review of random courier sign-in log sheets for November of 2022 revealed the laboratory did not document sample acceptability at receipt as follows: On 11/09/2022 Line 6 through line 16 did not have documentation of sample acceptability. Samples received: 2 urine, 7 tox (toxicology), 1 covid, 6 containers (bags/boxes) of blood samples, 2 unspecified On 11/10/2022 Line 6 through line 8 and line 10 through line 15 did not have documentation of sample acceptability. Samples received: 4 covid, 3 urine, 4 containers (bags/boxes) of blood samples, 12 unspecified On 11/15/2022 Line 9 through line 16 did not have documentation of sample acceptability. Samples received: 8 containers (bags/boxes) of blood samples, 8 unspecified 6. In an interview on 12/20/2022 at 1600 hours in the transition area, the Laboratory's Technical Consultant, after review of the data, confirmed the findings. D. Based on review of the laboratory's policies and procedures, review of manufacturer instructions for use for the Beckman Coulter Emit 2000 Valproic Acid Assay, review of laboratory's test logs for November of 2022 and staff interview, it was determined the laboratory failed to establish 2 to 8C specimen stability timeframe for valproic acid, one of one test without manufacturer established timeframes for specimen stability at 2 to 8C. Findings included: 1. Review of the laboratory's policy "Clinical Sample Processing", Appendix A revealed the following sample stability requirements for Valproic Acid: "RT(15-30C): ? hrs, Ref(2-8C): ? hrs, freeze at -20C for up to 1 year" 2. Review of manufacturer instructions for use for the Beckman Coulter Emit 2000 Valproic Acid Assay (10869946_G, 2019-05) revealed: "Serum or plasma samples may be refrigerated at 2-8C. For transporting, maintain the sample temperature at 2-8C. Samples may be frozen (-20C) for 1 year." There was no mention of sample's stability timeframe at 2 to 8C. 3. Review of laboratory's test logs for November of 2022 revealed the following patients were tested for Valproic Acid: Accession number: 221101BM0042 Collected on: 10/31/2022 Tested on:11/01/2022 Accession number: 221102BM0066 Collected on: 11/01/2022 Tested on:11/02/2022 Accession number: 221102BM0123 Collected on: 11/02/2022 Tested on:11/02/2022 Accession number: 221103BM0098 Collected on: 11/03/2022 Tested on:11/03/2022 Accession number: 221109BM0046 Collected on: 11/08/2022 Tested on:11/09/2022 Accession number: 221109BM0150 Collected on: 11/09/2022 Tested on:11/10/2022 Accession number: 221110BM0029 Collected on: 11/09/2022 Tested on:11/10/2022 Accession number:

	221111BM0058 Collected on: 11/10/2022 Tested on:11/11/2022 Accession number: 221111BM0068 Collected on: 11/11/2022 Tested on:11/11/2022 Accession number: 221115BM0048 Collected on: 11/14/2022 Tested on:11/15/2022 Accession number: 221118BM0013 Collected on: 11/17/2022 Tested on:11/18/2022 Accession number: 221122BM0025 Collected on: 11/21/2022 Tested on:11/22/2022 Accession number: 221123BM0011 Collected on: 11/22/2022 Tested on:11/23/2022 Accession number: 221123BM0014 Collected on: 11/22/2022 Tested on:11/23/2022 Accession number: 221123BM0104 Collected on: 11/23/2022 Tested on:11/23/2022 In an interview on 12 /20/2022 at 1310 hours in the office, the laboratory's Technical Consultant, after review of the data, confirmed the findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, procedures and shipment instructions to clients, review of laboratory's specimen stability studies, review of manufacturer package inserts/instructions for use, surveyor's observations and staff interview, it was determined the laboratory's Quality Assessment failed to identify, assess and correct problems with pre-analytic systems. Refer to D5311A, B, C and D.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, procedures and shipment instructions to clients, review of laboratory's specimen stability studies, review of manufacturer package inserts/instructions for use, surveyor's observations and staff interview it was determined the laboratory's Quality Assessment failed to include review of the effectiveness of corrective actions taken to resolve problems in pre-analytic systems. Refer to D5311A and B.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
A. Based on review of the facility's Reference Laboratory requirements for specimen transport, review of the laboratory's policies and procedures, review of laboratory's patient test records for January to December of 2022 and staff interview, it was determined the laboratory's policies and procedures failed to address packaging and shipping of samples at room temperature, one of three shipping conditions, as per Reference Laboratory's requirements. Findings included: 1. Review of the facility's Reference Laboratory requirements for specimen transport revealed the following samples were to be shipped at room temperature: Ova and Parasite Examination (ParaPack stool transport vials): "Storage Instructions: Maintain specimen at room temperature" Occult Blood, Fecal, Immunoassay: "Storage Instructions: Specimen in sampling bottle can be stored for 15 days at room temperature." 2. Review of the laboratory's policy "Send Out Testing" (last reviewed 10/31/2022) revealed no instructions for how to pack and ship specimens at room temperature. 3. Review of laboratory's patient test records for January to December of 2022 revealed the laboratory sent 1 Ova and Parasite Exam and 34 Occult Blood samples to the reference laboratory. 4. In an interview on 12/21/2022 at 1155 hours in the office, the laboratory's Technical Consultant, after review of the data, confirmed he findings. B. Based on random review of the laboratory's hematology quality control (QC) records for August to November of 2022, review of laboratory's policies and procedures, review of laboratory's patient test records and staff interview, it was determined the laboratory failed to follow its own policy for testing hematology controls every 8 hours for 1 of 29 randomly selected days reviewed, with patients' samples tested beyond the 8 hour laboratory defined QC interval. Findings included: 1. Random review of the laboratory's hematology QC records for August to November of 2022 revealed the laboratory did not perform QC every 8 hours on the following days: On 10/05/2022, Wednesday: Controls were tested 2 times that day Tested at: 0102 and 0103 hours Controls tested: Level 1 and Level 2 Tested at: 0745 and 0746 hours Controls tested: Level 2 and Level 3 There was no documentation of QC performance on the third/evening shift (after 1600 hours). 2. Review of laboratory's policies and procedures revealed: Policy: Quality Control - Control Ranges and Out of Control (last reviewed 10/31/2022) "Hematology and Coagulation instrumentation QC is run every 8-hour shift." There was no mention as to the number of controls required per shift, nor whether all three, or two of three passing controls were acceptable/required prior to patient testing. 3. Review of laboratory's patient test records for 10/05/2022 revealed the following patients' samples were tested on the third/evening shift (after 1600 hours), beyond the laboratory defined 8-hour QC interval: Accession: Tested at (hours): 221005BM0035 16:03 221005BM0038 16:03 221005BM0043 16:15 221005BM0046 16:15 221005BM0049 16:15 221005BM0050 16:15 221005BM0051 16:15 221005BM0052 16:15 221005BM0087 20:27 221005BM0088 20:27 221005BM0089 20:27 221005BM0090 20:39 221005BM0091 20:39 221005BM0092 21:15 221005BM0093 21:39 221005BM0094 20:51 221005BM0095 21:15 221005BM0096 23:39 221005BM0097 23:39 221005BM0098 23:39 221005BM0099 21:39 221005BM0100 21:39 221005BM0102 21:39 221005BM0103 21:39 221005BM0104 21:51 4. In an interview on 12/21/2022 at 1540 hours in the transition room, the laboratory's Technical Consultant, after review of the data, confirmed the findings. C. Based on review of laboratory's temperature charts and records for January to December of 2022 and staff interview it was determined the laboratory did not follow its own requirements for Monday's documentation of Minimum and Maximum temperatures for monitoring temperatures over the weekend. Findings included: 1. Review of laboratory's temperature charts revealed: "Temperature range is checked every working day and Min/Max temperatures must be noted down on Monday for monitoring temperatures over the weekend." 2. Review of the laboratory's

	temperature records for January to December of 2022 revealed there was no documentation of Minimum and Maximum temperatures on Mondays. 3. In an interview on 12/22/2022 at 1500 hours in the transition room, the laboratory's Technical Consultant confirmed the findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on surveyor's observations and review of the laboratory's centrifuge settings, review of laboratory's policies and procedures, review of patient test records and staff interview it was determined the laboratory failed to define and follow requirements for specimen centrifugation for the urine analysis microscopic exam, one of two microscopy procedures performed by the laboratory. Findings included: 1. Surveyor's observations and interview of moderate complexity testing person number 4 (MCTP4) on 12/20/2022 at 1430 hours in the laboratory revealed two centrifuges used in the preparation of microscopic exam urine samples: Drucker Diagnostics 642E Centrifuge Serial number (SN): 180913DN880 McKesson VariableSpeed Centrifuge SN: LT2011738 2. Review of the above centrifuges' settings revealed the two centrifuges were set at different centrifugation speeds: Drucker Diagnostics 642E Centrifuge Speed: 3330 RPM (revolutions per minute) McKesson VariableSpeed Centrifuge Speed: 2000 RPM 3. In an interview on 12/20/2022 at 1430 hours in the laboratory MCTP4 stated the specimen centrifugation for the urine analysis microscopic exam is set for 10 minutes on either of the above centrifuges. 4. Review of laboratory's procedure "Microscopic Urinalysis", last reviewed on 10/31/2022, revealed no specifications for centrifugation speed and/or time requirements. 5. Review of laboratory's patient test records revealed the laboratory performed 7043 urinalysis tests annually, with over 5000 microscopic urine exams. 6. In an interview on 12/20 /2022 at 1510 hours in the office, the laboratory's Technical Consultant, after review of the data, confirmed the findings. B. Based on surveyor's observations in the laboratory, random review of the laboratory's hematology quality control (QC) records for August to November of 2022, review of laboratory's policies and procedures, review of submitted Form 116 and staff interview it was determined the laboratory failed to define number and acceptability of controls in use for one of one

	hematology procedures. Findings included: 1. Surveyor's observations in the laboratory on 12/21/2022 at 1330 revealed the laboratory used 3 levels of hematology controls: Coulter 6C Cell Control Level 1 Lot:123174660 Expiration date: 2023-02-04 Coulter 6C Cell Control Level 2 Lot:123174660 Expiration date: 2023-02-04 Coulter 6C Cell Control Level 3 Lot:123174660 Expiration date: 2023-02-04 2. Random review of the laboratory's hematology QC records for August to November of 2022 revealed the laboratory was not consistent in performing all 3 levels of controls each time QC was performed. For example: On 08/23/2022, Tuesday: Controls were tested 3 times that day Tested at: 0106 and 0117 hours Controls tested: Level 1 and Level 3 Tested at: 0852 hours Controls tested: Level 1, Level 2 and Level 3 Tested at: 1657 and 1658 hours Controls tested: Level 2 and Level 3 On 08/27/2022, Saturday: Controls were tested 2 times that day Tested at: 0111 and 0112 hours Controls tested: Level 1 and Level 3 Tested at: 0943 and 0944 hours Controls tested: Level 1, Level 2 and Level 3 On 09/30/2022, Friday: Controls were tested 3 times that day Tested at: 0111 and 0115 hours Controls tested: Level 1 and Level 2 Tested at: 0823, 0824 and 0825 hours Controls tested: Level 1, Level 2 and Level 3 Tested at:1708 hours Controls tested: Level 1 On 10/05/2022, Wednesday: Controls were tested 2 times that day Tested at: 0102 and 0103 hours Controls tested: Level 1 and Level 2 Tested at: 0745 and 0746 hours Controls tested: Level 2 and Level 3 3. In an interview on 12 /21/2022 at 1330 in the laboratory, the laboratory's Technical Consultant stated that minimum of 2 levels of hematology controls were being tested every 8 hours, and that Tuesday through Friday the laboratory performed testing on 3 shifts (24 hours operations). 4. Review of laboratory's policies and procedures revealed: Policy: Quality Control - Control Ranges and Out of Control (last reviewed 10/31/2022) "Hematology and Coagulation instrumentation QC is run every 8-hour shift." There was no mention as to the number of controls required per shift, nor whether all three, or two of three passing controls were acceptable/required prior to patient testing. Policy: DXH 600 Hematology Analyzer (last reviewed 10/27/2021) "Frequency: Quality Control specimens should be run and results confirmed to be within acceptable limits prior to reporting patient results. Controls should also be run: ... According to your laboratory's quality control program" There was no mention as to the number of controls required per shift, nor whether all three, or two of three passing controls were acceptable/required prior to patient testing. 5. Review of laboratory's submitted Form 116 revealed the laboratory performed 20,095 hematology tests annually. 6. In an interview on 12/21/2022 at 1345 hours in the laboratory, the Technical Consultant, after review of the policies and data, confirmed the findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for use for the Prostate Specific Antigen (PSA) test, review of laboratory's policies and procedures, random review of patient records for November and December of 2022 and staff interview, it was determined the laboratory failed to follow manufacturer instructions for testing PSA on patients older than 50 years of age for 9 of 42 patients reviewed. Findings

	included: 1. Review of the manufacturer's instructions for use for the Prostate Specific Antigen (PSA) test (Access Hybritech PSA document 85067 M, May 2020) revealed: "Intended use ... This devise is indicated for the measurement of serum PSA in conjunction with digital rectal examination (DRE) as an aid in detection of prostate cancer in men 50 years or older. ...This devise is further indicated for the serial measurement of PSA to aid in the prognosis and management of patients with prostate cancer." 2. Review of laboratory's policy "PSA Assay" (last reviewed October of 2022) revealed: "INTENDED USE ... This devise is indicated for the measurement of serum PSA in conjunction with digital rectal examination (DRE) as an aid in detection of prostate cancer in men 50 years or older. ...This devise is further indicated for the serial measurement of PSA to aid in the prognosis and management of patients with prostate cancer." 3. Random review of patient records for November and December of 2022 revealed the following 9 patients, younger than 50 years of age without documented diagnosis of cancer, were tested for PSA: Sample ID: 5408CC9163 Patient's age: 37 Tested on: 11/11/2022 Result: 0.54 ng/mL (nanograms per milliliter) Sample ID: 6691CB445 Patient's age: 30 Tested on: 11/11/2022 Result:0.46 ng/mL Sample ID: 5211CB715 Patient's age: 41 Tested on: 12/16/2022 Result: 0.77 ng/mL Sample ID: 5190CB3164 Patient's age: 47 Tested on: 12/17/2022 Result: 0.72 ng/mL Sample ID: 1938CB361 Patient's age: 28 Tested on: 12/17/2022 Result: 0.70 ng/mL Sample ID: 5211CA11822 Patient's age: 38 Tested on: 12/17/2022 Result: 0.51 ng /mL Sample ID: 5211CB703 Patient's age: 26 Tested on: 12/17/2022 Result: 0.36 ng /mL Sample ID: 5211CB714 Patient's age: 34 Tested on: 12/17/2022 Result: 0.50 ng /mL Sample ID: 5211CB705 Patient's age: 27 Tested on: 12/17/2022 Result: 0.63 ng /mL Review of the above patients' requisition records for diagnosis revealed none of the patients had a prior diagnosis of prostate cancer. 4. In an interview on 12/20/2022 at 1050 hours in the transition room, the laboratory's Technical Consultant, after review of the data, confirmed the findings.
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 the surveyor's direct observation, the laboratory's QC logs in 2022, temperature logs from June 2022 to November 2022, and confirmed in an interview found the laboratory failed to follow the manufacturer's instructions for storage temperature for eight of 50 days reviewed for four of four control lot numbers. The findings were: 1. Review of the laboratory's QC logs in 2022 revealed the laboratory used the following MAS Omni Controls. OmniCore Immunoassay Omni Immune Pro Omni Cardiac 2 Further review of the laboratory's QC logs in 2022 revealed MAS Omni Controls were used for four of four chemistry analyzers. OmniCore Immunoassay on Beckman Coulter AU680 (SN: 2018016348) Omni Immune Pro and Omni Cardiac on Beckman Coulter Unicel DxI 600 (SN: BB51913) Omni Immune Pro and Omni Cardiac on Beckman Coulter Unicel DxI 800 (SN: 609452) Omni Immune Pro on Siemens Immulite 2000 XPi (SN: H2177) 3. Surveyor's direct

	observation on 12/22/22 at 2:00 pm in the freezer#5 White where QC controls stored revealed three of three MAS Omni Controls. OmniCore Immunoassay Lot# OPRO4063 Exp. 2024-06-30 Omni Cardiac Lot# OCRD2503 Exp. 2025-03-31 Omni Immune Pro Lot# OPRO2302 Exp. 2023-02-28 4. Surveyor's direct observation on 12 /22/22 at 2:00 pm for MAS Omni control bottles revealed the storage temperature was -25 to -15C. 5. Review the laboratory's temperature logs in from June 2022 to November 2022 revealed freezer#5 White with Min/Max acceptable ranges was -30 to -15C. 6. Further review of the laboratory's temperature logs from June 2022 to November 2022 revealed the temperatures were out of manufacturer's ranges for eight of 50 days reviewed. 10/01/2022 -26.0C 10/28/2022 -26.3C 10/29/2022 -26.9C 11/04 /2022 -25.4C 11/05/2022 -25.5C 11/09/2022 -25.2C 11/10/2022 -25.2C 11/23/2022 -25.4C 7. Review the total patient volume for above dates that QC was performed on all four chemistry instruments. 10/01/2022 41 total patients 10/28/2022 84 total patients 10/29/2022 64 total patients 11/04/2022 146 total patients 11/05/2022 86 total patients 11/09/2022 122 total patients 11/10/2022 189 total patients 11/23/2022 146 total patients 8. An interview with the technical consultant (TC) on 12/22/22 at 2:55 pm in the transitional room confirmed the above findings. Key: QC=Quality Control
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 the review of the manufacturer's manuals, the laboratory's maintenance logs for 2022, and confirmed in an interview found the laboratory failed to perform quarterly maintenance required by the manufacturer for two of four chemistry analyzers. a. one of four quarterly maintenance on Siemens Immulite 2000 XPi (SN: H2177) b. three of four quarterly maintenance on Beckman Coulter AU 680 Chemistry analyzer (SN: 2018016348) The findings were: a. Siemens Immulite 2000 XPi 1. Review of the manufacturer's manual (Immulite 2000 System Operator's Guide) under 5 Performing Maintenance revealed Quarterly Maintenance, "Replacing the CO2 Scrubber. Substrate Reservoir Maintenance." 2. Further review of the manufacturer's manual under page 5-27 Quarterly Maintenance revealed, "For maintenance records that you can copy and use to keep track of maintenance items, see Worksheets, page 5-32." 3. Review of the laboratory's maintenance logs for 2022 revealed the laboratory failed to perform one of four quarterly maintenance for Siemens Immulite 2000 XPi chemistry analyzer. b. Beckman Coulter AU 680 Chemistry analyzer 4. Review of the manufacturer's Instructions for Use AU680 Chemistry Analyzer (PN B04779AB (June 2015)) under Chapter 6 page 6-57 Quarterly Maintenance revealed "Perform the following procedures quarterly (every three months). Clean the Air Filters Inspect and, if Needed, Replace the Deionized Water Filter, Sample Probe Filter, and Replace the O-Ring Replace the Wash Solution Roller Tubing" 5. Review of the laboratory's maintenance logs for 2022 revealed the laboratory failed to perform three of four quarterly maintenance for Beckman Coulter AU680 chemistry analyzer. 6. An interview with the technical consultant (TC) on 12 /22/22 at 2:00 pm in the transitional room confirmed the above findings.
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 review of the laboratory's temperature records for January to December of 2022, surveyor's observations, review of corrective action documentation for the same interval, review of reagent storage requirements and staff interview, it was determined the laboratory failed to document corrective action for 47 of 47 instances the temperature was recorded out of laboratory's defined range. Findings included: 1. Review of the laboratory's temperature records for January to December of 2022 revealed the laboratory defined acceptable freezer temperature ranges as -25C to -15 C. 2. Further review of the above temperature records revealed the following temperatures were out of laboratory defined range: Freezer: Pre - R4 Acceptable temperature range defined as: -25C to -15C Date: Temperature recorded: 01/17/2022 -25.2C 02/01/2022 -25.8C Freezer: White #2 Acceptable temperature range defined as: -25C to -15C Date: Temperature recorded: 07/05/2022 -25.3C 08/04/2022 -25.6C Freezer: Deep Freezer Acceptable temperature range defined as: -25C to -15C Date: Temperature recorded: 02/14/2022 24.2C 02/15/2022 23.0C 02/16/2022 19.9C 02/17 /2022 23.4C 02/18/2022 18.3C 02/19/2022 20.8C 02/21/2022 20.1C 02/22/2022 23.6 C 02/23/2022 19.4C 02/24/2022 20.9C 02/25/2022 21.2C 02/26/2022 17.8C 02/28 /2022 21.9C Temperatures in February were recorded as positive values. 03/01/2022 22.0C 03/02/2022 21.2C 03/03/2022 23.6C 03/04/2022 20.1C 03/05/2022 23.3C 03/07 /2022 21.6C 03/08/2022 19.9C 03/09/2022 18.3C 03/10/2022 18.7C 03/11/2022 23.6 C 03/12/2022 21.7C 03/14/2022 19.8C 03/15/2022 19.7C 03/16/2022 19.1C 03/17 /2022 19.8C 03/18/2022 19.7C 03/19/2022 18.6C 03/21/2022 20.3C 03/22/2022 19.7 C 03/23/2022 18.6C 03/24/2022 19.7C 03/25/2022 18.9C 03/26/2022 23.2C 03/28 /2022 19.7C 03/29/2022 23.8C 03/30/2022 20.3C 03/31/2022 23.2C Temperatures in March were recorded as positive values. 08/18/2022 -25.2C 08/23/2022 22.8C (positive value) 08/31/2022 23.5C (positive value) 3. Surveyor's observation on 12/22 /2022 at 14:45 in the laboratory revealed the following items stored in the above freezers: a. "Pre - R4" Freezer stored: Pre-set-up ice blocks and processed panels Storage requirements were not defined b. "White #2" Freezer stored: - Applied Biosystems TaqMancCustom PreAmp Pool Lot 2211947, Expiration 2023-11-07 Storage requirements: -10 to -30C - Applied Biosystems MagMax Viral/Pathogen Ultra Enzyme Mix Lot 2208032, Expiration 2023-07-31 Storage requirements: -15 to -25C - Applied Biosystems TaqMan Copy Number Reference Assay Lot 21080070, Expiration 2023-03-12 Storage requirements: -15 to -25C - TaqMan OpenArray Real-Time PCR Master Mix Lot 01306861, Expiration 2023-04-30 Storage requirements: -15 to -25C - TaqPath 1-Step Multiplex Master Mix Lot 01317462, Expiration 2023-08-17 Storage requirements: -10 to -30C c. "Deep Freezer" stored: Ice blocks/packs Storage requirements were not defined 4. Review of corrective action documentation for January to December of 2022 revealed no corrective action was documented for any of the above out of range temperature records. 5. In an interview on 12/22/2022 at 1500 hours in the transition room, the laboratory's Technical Supervisor, 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 policies and procedures, review of laboratory's quality control records, review of instrument settings, review of laboratory's temperature logs and staff interview it was determined laboratory's Quality Assessment failed to identify and correct issues in analytic systems. Refer to D5401 (A, B and C), D5403 (A and B), D5411 and D5785.
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: Based on review of a sampling of patient's final reports for tests performed in the specialty of microbiology and staff interview it was determined the laboratory failed to include on the final report a complete list of interpretation values for 2 of 4 microbiology tests performed by molecular methods. Findings included: 1. Review of a sampling of patient's final reports for tests performed in the specialty of microbiology revealed the following test reports were issued: UTI-ABR Molecular Assay Wound-ABR Molecular Assay Respiratory Pathogen Panel (RPP) Altru Dx COVID 19 RT PCR 2. Further review of the above tests' final reports revealed the following reports were missing a complete list of interpretation values: UTI-ABR Molecular Assay - no definition of "Not detected" Wound-ABR Molecular Assay - no definition of "Not detected" 3. In an interview on 12/22/2022 at 1345 hours in the office, the laboratory's Technical Supervisor, after review of the reports, confirmed the findings.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of a sampling of patient's final reports for tests performed in the specialty of microbiology and staff interview it was determined the laboratory failed to include on the final report normal values for 4 of 4 microbiology tests performed by molecular methods. Findings included: 1. Review of a sampling of patient's final

	reports for tests performed in the specialty of microbiology revealed the following test reports were issued: UTI-ABR Molecular Assay Wound-ABR Molecular Assay Respiratory Pathogen Panel (RPP) Altru Dx COVID 19 RT PCR 2. Further review of the above tests' final reports revealed the following reports were missing information defining normal values: UTI-ABR Molecular Assay Wound-ABR Molecular Assay Respiratory Pathogen Panel (RPP) Altru Dx COVID 19 RT PCR 3. In an interview on 12/22/2022 at 1345 hours in the office, the laboratory's Technical Supervisor, after review of the reports, confirmed the findings.
D6039	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(1) The technical consultant is responsible for-- (b)(1) Selection of test methodology appropriate for the clinical use of the test results; This STANDARD is not met as evidenced by: Based on surveyor's observations and review of the laboratory's centrifuge settings, review of laboratory's policies and procedures, review of patient test records and staff interview it was determined the laboratory's Technical consultant failed to ensure appropriate centrifugation methodology for microscopic urine analysis was selected. Refer to D5403A.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on surveyor's observations in the laboratory, random review of the laboratory's hematology quality control (QC) records for August to November of 2022, review of laboratory's policies and procedures, review of submitted Form 116 and staff interview it was determined the laboratory's Technical Consultant failed to ensure analytic QC performance parameters were established and followed. Refer to D5403B.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of laboratory's quality assessment records, review of manufacturer instructions for use, surveyor's observations and staff interview, it was determined the Laboratory Director failed to

	ensure laboratory's Quality Assessment identified and corrected failures in quality for pre-analytic and analytic systems. Refer to D5391, D5393 and D5791.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for 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 records for January to December of 2022, surveyor's observations, review of corrective action documentation for the same interval, review of reagent storage requirements and staff interview, it was determined the laboratory's Technical Supervisor failed to ensure remedial actions were taken. Refer to D5785.