Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0663089	10/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pediatrics Associates	8355 Walnut Hill Ln # 205, Dallas, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An entrance conference was held 10/30/2019 with the Technical Consultant. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 10/30/2019 through 10/31/2019, this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1215 Hematology; 493.1403 Laboratories performing moderate complexity testing; laboratory director; 493.1409 Laboratories performing moderate complexity testing; technical consultant An exit conference was held on 10/31/2019 with the Technical Consultant. An opportunity for questions and comments was provided. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) records and staff interview the laboratory failed to test hematology PT samples in the same manner as it tests patient specimens for 3 of 3 testing events in 2018 (E-1, E-2, E-3) and 2 of 2 (E-1, E-2) testing events in 2019. Findings: 1. Review of API Attestation Statement revealed the following: "PERSON(S) PERFORMING THE

	TEST- We certify that as closely as possible, these proficiency testing samples were tested in the same manner as possible." Further review of the attestation statement revealed the following testing persons (TP) performed testing and the corresponding PT sample: 2018 E-1: TP-1, TP-2, TP-3, TP-4, TP-5, TP-6, TP-8 all 5 hematology samples 2018 E-2: TP-2, TP-3, TP-5 hematology sample #5 TP-8 hematology sample #2 TP-4 hematology sample #3 TP-1 all 5 hematology samples 2018 E-3: TP-1 and TP-3 all 5 hematology samples and blood cell ID TP-2, TP-6, TP-7 all hematology samples TP-4 hematology sample #3 TP-8 hematology sample #3 2019 E-1 TP-1 and TP-3 all 5 hematology samples and blood cell ID TP-4 hematology sample #s 1 and 2 TP-6 hematology sample #s 3, 4 and 5 TP-7 hematology sample #s 1, 2 and 3 2019 E-2 TP-1 and TP-3 all 5 hematology samples and blood cell ID TP-2, TP-4, TP-5, TP-6, TP-7 all 5 hematology samples The laboratory failed to test hematology PT samples in the same manner as it tests patient specimens. 3. During an interview on 10/30 /2019 at 10:51 am, the technical consultant (TC) stated that all testing persons participate in proficiency testing. He stated that was his way of assessing competency and rotating PT. The TC stated that the same PT samples were tested by different testing persons but only one result was reported. This confirmed the laboratory failed to test hematology PT samples in the same manner as it tested patient specimens.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observations, review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records, manufacturer's instructions, quality control (QC) records, maintenance logs, corrective action logs, patient test reports, and confirmed in interview, the laboratory failed to meet the requirements for the specialty of hematology as evidenced by: 1. The laboratory failed to test hematology PT samples in the same manner as it tests patient specimens for 3 of 3 testing events in 2018 (E-1, E-2, E-3) and 2 of 2 (E-1, E-2) testing events in 2019. Refer to D2006. 2. The laboratory failed to follow manufacturer's instructions for staining blood smears for CBC differentials. Refer to D5411, II. 3. The laboratory failed to follow manufacturer's instructions for flags on the CELL-DYN 1800 hematology analyzer for 3 of 40 patients in 2019 (random review 10/12/2019 through 10/30/2019). Refer to D5411, III. 4. The laboratory failed to ensure reagents, QC (quality control) were labeled with new expiration dates according to the manufacturer. Refer to D5415. 5. The laboratory failed to ensure reagents, QC (quality control) did not exceed their expiration dates. Refer to D5417. 6. The laboratory failed to follow manufacturer's instructions for performing weekly and monthly maintenance for 14 of 14 weeks and 1 of 3 months in 2018 (October through December) and 38 of 38 weeks and 5 of 9 months in 2019 (January through September). Refer to D5429. 7. The laboratory failed to test and document for intended reactivity (QC) for QuickLink III stain for CBC (complete blood count) peripheral blood smears for each day of use in 2018 and 2019. Refer to D5473. 8. The laboratory failed to document corrective actions for 5 of 5 days that included failures in 2018 and 3 of 3 days in 2019. Refer to D5781. 9. The laboratory failed to evaluate all patient test results after performing test system

	adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 8 of 8 patients in 2019 (02/2019, 10/2019 random review). Refer to D5783.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, and staff interview, it was revealed the laboratory failed to have a procedure used to perform or documentation of a competency assessment for 1 of 1 technical consultants (TC-1). Findings: 1. A review of the laboratory's policies revealed the laboratory failed to have a policy of when and how a competency assessment was to be performed on the general supervisor. 2. Review of personnel records for TC-1 revealed there were no documented annual competency assessment for the duties performed as a TC. Review of personnel files for TC-1 revealed a hire date of 05/09/2004. 3. During an interview on 10/30/2019 at 10:25 am, the TC confirmed the above 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: I. Based on review of laboratory policy, manufacturer's instructions, TAXO A logs, patient test records, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for sending positive streptococcus results for confirmation for 1 of 1 patients in 2018 (random review December) and 10 of 10 patients in 2019 (random review September to October). Findings: 1. Review of "POLICY AND PROCEDURE FOR QUALITY CONTROL IN IDENTIFICATION OF GROUP A STREPTOCOCCI USING BACITRACIN/TAXO A DISCS AND SUBCULTURING OF CONTROL ORGANIMS-GROUP A & B" laboratory policy revealed: "Limitation of the Procedure The TAXO A disc test is presumptive, and a positive result should be followed with more specific physiological and/or serological tests." 2. Review of "BD BBL Taxo A Discs for Differentiation of Group A Streptococci" package insert revealed: "LIMITATIONS OF THE PROCEDURE The TAXO A disc test is presumptive, and a positive result should be followed with more specific physiological and/or serological tests." 3. Review of TAXO A logs revealed patients who tested positive for group A beta-hemolytic streptococci. The following is a random sampling of presumptive positive patients who were not sent for further testing by the laboratory in 2018 and 2019: 12/23/2018 Patient Lab Order ID 304217 09/30/2019 Patient Lab Order ID 343581 10/07/2019 Patient Lab Order ID 344345 10 /08/2019 Patient Lab Order ID 344726 10/10/2019 Patient Lab Order ID 344968 10/18 /2019 Patient Lab Order ID 345826 10/18/2019 Patient Lab Order ID 345826 10/23

/2019 Patient Lab Order ID 346681 10/24/2019 Patient Lab Order ID 346858 10/25 /2019 Patient Lab Order ID 346922 10/29/2019 Patient Lab Order ID 347488 10/29 /2019 Patient Lab Order ID 347408 4. During an interview on 10/30/2019 at 1:10 pm, testing person-3 stated that providers are notified of patients who have positive culture for group A streptococcus and that they are not sent out for confirmation, confirming the above findings. II. Based on review of laboratory policy, manufacturer's instructions and confirmed in interview, the laboratory failed to follow manufacturer's instructions for staining blood smears for CBC differentials. Findings: 1. Review of the laboratory's policy for manual differentials revealed: "Procedure Making a blood smear ... 9. Dip each slide to be processed for five, one second dips into the fixative solution. Allow excess reagent to drain or blot slide. 10. Repeat this procedure substituting solution I and solution II respectively 11. Rinse slides with deionized water and allow to air dry." 2. Review of QuickLink III Insert Sheet revealed: "TECHNIQUE 1. Transfer each solution into coplin jars or staining dishes and keep covered when not in use. 2. Prepare slides as instructed under Specimen Collection. 3. Dip each slide to be processed for five, one second dips into the Fixative Solution. Allow excess reagent to drain or blot slide. 4. Repeat this procedure substituting Solution I and Solution II respectively. 5. Rinse slides with deionized water and allow to dry ..." 3. During an interview on 10/30/2019 at 3:15 pm, testing person-3 was asked what the procedure for staining slides and she stated that slides were dipped 10 times in each solution 10 times and then rinsed with water. Testing Person-1 stated that slides were rinsed with tap water. The laboratory failed to follow manufacturer's instructions for staining blood smears. 4. The annual volume of blood smears in 2019 was 43 smears. 5. During the exit interview on 10/31/2019 at 12:06 pm, testing person-1 confirmed the above findings. III. Based on review of laboratory policy, manufacturer's instructions, patient test reports, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for flags on the CELL-DYN 1800 hematology analyzer for 3 of 40 patients in 2019 (random review 10/12/2019 through 10/30/2019). Findings: 1. Review of "POLICIES AND PROCEDURES FOR CBC TESTING" laboratory policy revealed: "FLAGGED DIFFERENTIAL PROTOCOL: A flag of R1, R, R3, or M refers to suspect cell populations. When this occurs: 1. Check to make sure you collected enough sample 2. Wait an additional 5-10 minutes and remix the sample well before retesting [sic] If the differential remains flagged after retesting the sample follow the protocol outlined here: For sick child visits: When an auto-differential is flagged, the testing personnel will replace flagged differential results with "Not Done" in the EHR. "Not Done" will signal to the physician that the differential has flags. In addition, the Cell-Dyn printed CBC report will be delivered to the physician. The physician then has the opportunity to request a manual differential for that sample." For Well Child Visits: When an auto-diff is flagged, if the WBC Gran, Lymph, Mid result is out of range (high or low), the testing personnel will replace flagged differential results with "Not Done" in the HER. The Cell-Dyn printed on the CBC report will be delivered to the physician. The physician then has the opportunity to request a manual differential for that sample. If an auto-differential is flagged and the WBC, Gran, Lymph, Mid result is normal (within the reference range), the flagged results will be entered into the patient's EHR and no further action is necessary. The physician can request a manual differential for any patient at any time. The flagged results were left to the physician's discretion not to follow manufacturer's instructions to ensure accurate and reliable test results. 2. Review of Cell-Dyn 1800 operator's manual revealed: "Introduction ... Instructions for interpreting all flags, numeric, and histogram data must be incorporated into your laboratory's procedure manual and used to determine the need for further action and /or review of results ... Parameter Data Flags The CELL-DYN 1800 displays a parameter flagging message when a sample exhibits any reportable abnormalities. The

	messages are created when one of the following sample abnormalities is present: Dispersal data alerts Suspect parameter flags Suspect population flags ... Suspect Population Flags These suspect flags are generated when the evaluation of measured WBC data by the instrument indicates the possible presence of an abnormal subpopulation. Follow your laboratory's protocol whenever a suspect population flag is present. Instructions for interpreting flags should be incorporated into the laboratory's review criteria for abnormal results. Increased or decreased lytic action can also generated flags. The name of each flag, how it is displayed, the cause of the flag, and the action to be taken are given in the following explanations: NOTE: RM means more than one alert within the same subpopulation. Flag: LYM R1 is displayed between the absolute and the present results of LYM. Cause: This flag can be caused by: Lymphocytosis Lymphopenia Cryoglobulins Shift in WBC cell distribution due to EDTA anticoagulant equilibration. Flag: LYM R2 is displayed between the absolute and the present results of LYM. Cause: This flag is caused by: Lymphocytosis Lymphopenia Blasts Variant lymphocytes Plasma cells Basophilia Shift in WBC cell distribution due to EDTA anticoagulant equilibration. Flag: MID R2 or RM is displayed between the absolute and percent results of MID. Cause: This flag can be caused by: Lymphocytosis Lymphopenia Blasts Variant lymphocytes Plasma cells Basophilia Monocytosis Shift in WBC cell distribution due to EDTA anticoagulant equilibration. Flag: MID R3 or RM is displayed between the absolute and percent results of MID. Cause: This flag can be caused by: Eosinophilia Blasts Agranular neutrophils Plasma cells Basophilia Bands Shift in WBC cell distribution due to EDTA anticoagulant equilibration. Flag: GRAN R3 or RM is displayed between the absolute and percent results of GRAN. Cause: This flag can be caused by: Granulocytes Neutropenia Eosinophilia Agranular neutrophils Bands Shift in WBC cell distribution of EDTA anticoagulant equilibration. Flag: GRAN R4 or RM is displayed between the absolute and percent results of GRAN. Cause: This flag can be used by: Hypersegmented neutrophils Granulocytosis Neutropenia Immature granulocytes Action: For all of the above Suspect Population Flags, check the specimen for clots or agglutination. Rerun specimen 20 minutes after collection. Follow your laboratory's review criteria or review a stained smear to confirm the results. Redraw and rerun the specimen as required." 3. Review of patient Cell-Dyn 1800 hematology analyzer test reports and final LIS reports revealed patient test results with flags were reported in October 2019 (random review). The following flagged results were reported: 10/23/2019 Patient ID: 12346 at 11:50 hours, "R2" flag on the LYM and % LYM parameters Patient ID: 62504 at 10:42 hours, "R4" flag on the GRAN and % GRAN parameters Patient ID: 62543 at 10:41 hours, "R3" flag on the GRAN and % GRAN parameters 4. During an interview on 10/31/2019 at 10:20 am, testing person-1 (TP-1) stated that flags could not be deleted from the results when they cross into the LIS system. TP-1 stated that the "not done" was done when they used to manually enter the results into the electronic medical record (EMR). He also stated that when results are transmitted from the LIS to the EMR the process is slow, so the instrument results are given to the provider to review. TP-1 stated that the flags are not blacked out and it is up to the provider to order the manual differential. This confirmed the laboratory failed to follow manufacturer's instructions to ensure accurate and reliable test results.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)

	Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, and confirmed in interview the laboratory failed to ensure reagents, QC (quality control) were labeled with new expiration dates according to the manufacturer. Findings: 1. Review of CDS NextGeneration Hematology Control package insert revealed: "STORAGE AND STABILITY ... Open vial stability is 14 days after opening when returned to the refrigerator after each use." 2. During a tour of the laboratory on 10/30/2019 at 3:15 pm, the surveyor observed the following opened hematology control reagents in the refrigerator: High level, lot #31909-13 (manufacturer's expiration date 01/20/2020), open date 10/10/19 Normal level, lot #31909-12 (manufacturer's expiration date 01/20 /2020), open date 10/10/19 Low level, lot #31909-11 (manufacturer's expiration date 01/20/2020), open date 10/10/19 The laboratory failed to document the new expiration date according to the manufacturer. 3. During an interview on 10/30/2019 at 3:15 pm, testing person-3 stated that the expiration date was "15 days" after opening. 4. During the exit interview on 10/31/2019 at 12:06 pm, the technical consultant confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, and confirmed in interview the laboratory failed to ensure reagents, QC (quality control) did not exceed their expiration dates. Findings: 1. Review of CDS NextGeneration Hematology Control package insert revealed: "STORAGE AND STABILITY ... Open vial stability is 14 days after opening when returned to the refrigerator after each use." 2. During a tour of the laboratory on 10/30/2019 at 3:15 pm, the surveyor observed the following opened hematology control reagents in the refrigerator: High level, lot #31909-13 (manufacturer's expiration date 01/20/2020), open date 10/10/19 Normal level, lot #31909-12 (manufacturer's expiration date 01/20/2020), open date 10/10/19 Low level, lot #31909-11 (manufacturer's expiration date 01/20/2020), open date 10/10 /19 The laboratory failed to ensure reagents did not exceed their expiration dates. 3. During an interview on 10/30/2019 at 3:15 pm, testing person-3 stated that the expiration date was "15 days" after opening. 4. During the exit interview on 10/31 /2019 at 12:06 pm, the technical consultant confirmed the above 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 manufacturer's instructions, review of maintenance logs, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for performing weekly and monthly maintenance for 14 of 14 weeks and 1 of 3 months in 2018 (October through December) and 38 of 38 weeks and 5 of 9 months in 2019 (January through September). Findings: 1. Review of Cell-Dyn 1800 operator's manual revealed weekly and monthly maintenance required to be performed on the hematology analyzer. The weekly maintenance tasks consisted of "Auto Clean" and "Clean Aspiration Probe Exterior." The monthly maintenance tasks consisted of "Rinse Lyse Inlet Lines" and "Rinse Reagent Inlet Lines." 2. Review of the Cell-Dyn 1800 maintenance log for the hematology analyzer located on the first floor (serial #21840AY) revealed the laboratory failed to perform the "Clean Aspiration Probe Exterior" task on the following weeks in 2018 and 2019: 10/01/2018, 10/08/2018, 10 /15/2019, 10/22/2018, 10/29/2018, 11/5/2018, 11/12/2018, 11/19/2018, 11/26/2018, 12 /03/2018, 12/10/2018, 12/17/2018, 12/24/2018, 12/31/2018, 01/07/2019, 01/14/2019, 01/21/2019, 01/28/2019, 02/04/2019, 02/11/2019, 02/18/2019, 02/25/2019, 03/04 /2019, 03/11/2019, 03/18/2019, 03/25/2019, 01/04/2019, 04/08/2019, 04/15/2019, 04 /22/2019, 04/29/2019, 05/06/2019, 05/13/2019, 05/20/2019, 05/27/2019, 03/06/2019, 06/10/2019, 06/17/2019, 06/24/2019, 07/01/2019, 07/08/2019, 07/15/2019, 07/22 /2019, 07/29/2019, 08/05/2019, 08/12/2019, 08/19/2019, 08/26/2019, 09/02/2019, 09 /09/2019, 09/16/2019, 09/23/2019 Review of the Cell-Dyn 1800 maintenance log for the hematology analyzer located on the first floor (serial #21840AY) revealed the laboratory failed to perform the monthly maintenance tasks on the following months in 2018 and 2019: 12/2018, 02/2019, 03/2019, 04/2019, 06/2019, 09/2019 3. During the exit interview on 10/31/2019 at 12:06 pm, the technical consultant confirmed the laboratory failed to perform weekly and monthly maintenance as required by the manufacturer.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, manufacturer's instructions, quality control (QC) records, and confirmed in interview, the laboratory failed to test and document for intended reactivity (QC) for QuickLink III stain for CBC (complete blood count) peripheral blood smears for each day of use in 2018 and 2019. Findings: 1. Review of the laboratory's procedure for manual differential and platelet estimate for CBC (complete blood counts) flags revealed: "Quality Control Slide The RBC's should appear buff red to orange The WBC's nucleus should be blue with a lighter staining of the cytoplasm Platelets nucleus should be blue with a lighter staining of the cytoplasm" 2. Review of QuickLink III Insert Sheet revealed: "Stained Specimen Results Specimen Erythrocyte Cytoplasm pink Specimen Leukocytes Granular Polymorphonuclear Neutorphils Nucleus purple Granules red-lilac Cytoplasm light pink Specimen Leukocytes Granular Polymorphonuclear Eosinophils Nucleus dark blue Granules red/orange Cytoplasm medium blue Specimen Leukocytes Granular Polymorphonuclear Basophils Nucleus dark blue Granules dark purple Cytoplasm

	light blue Specimen Monocytes Nucleus violet Cytoplasm light blue Specimen lymphocytes Nucleus violet Cytoplasm medium blue Specimen Platelets Granules purple Cytoplasm lilac" 3. The laboratory was asked for stain QC records, none were provided. The laboratory failed to test and document for intended reactivity (QC) for QuickLink III stain for CBC (complete blood count) peripheral blood smears 4. The laboratory had an annual volume of 43 CBC blood smear differentials in 2019. 5. During an interview on 10/30/2019 at 3:15 pm, technical consultant stated that QC for CBC blood smear smears were not performed, confirming the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Quality Control (QC) records for the Cell-Dyn 1800 hematology analyzer, corrective action logs, and confirmed in interview, the laboratory failed to document corrective actions for 5 of 5 days that included failures in 2018 and 3 of 3 days in 2019. 1. Review of laboratory policy for CBC's revealed: "Quality Control: Frequency: Three levels of CDS 3PD Hematology Control testing will be performed once every 24 hours. Procedure ... 4. Verify that the results are acceptable. NOTE: Out-of-range results are displayed in inverse video on the screen and underlined on the printout with an out-of-range indicator. 5. If results are unacceptable, repeat the run. If the results are still unacceptable, refer to the Operator's Manual Section 11: Quality Control for troubleshooting. 6. After troubleshooting retest the control. If still out of range, call Preferred Biomed for service. 7. Repeat procedure for each control level L, N, and H. If two out of three levels are within patient range testing may be reported. However, all effort should be made to identify the problem with the one level that is out of range. If more than one control level is out of range do not report patient results." The policy failed to include documentation of corrective actions for QC failures. 2. Review of Cell-Dyn 1800 (Serial #21840AY) QC records revealed the laboratory failed to document corrective actions for QC failures in 2018 and 2019 on the following dates and times: 12/02 /2018 Low level QC lot #L8295, expiration date 02/18/2019 9:49 am failure for HGB, MCH, MCHC 9:53 am QC passed Normal level lot #N8295, expiration date 02/18 /2019 9:50 am failure for WBC, RBC, HGB, HCT, MCH, MCHC, PLT 9:54 am failure for WBC, RBC, HGB, HCT, PLT 12/05/2018 Normal level lot #N8295, expiration date 02/18/2019 8:55 am failure for WBC, *MID, GRAN, %L, %G, RBC, HGB, HCT, MCH, PLT 8:57 am QC passed 12/20/2018 Normal level lot #N8295, expiration date 02/18/2019 9:09 am failure for RBC, HCT 9:12 am QC passed 12/21 /2018 Normal level lot #N8295, expiration date 02/18/2019 9:01 am failure for HCT, MCV 9:03 am QC passed 12/22/2018 Low level lot #L8295, expiration date 02/18 /2019 9:13 am failure for MCV 9:16 QC passed 9:18 failure for WBC, LYM, *MID, GRAN, %L, %G, RBC, HGB, HCT, MCH, MCHC, PLT QC lot #31906, expiration

	date 10/19/2021 09/08/2019 Low level 9:27 am failure for WBC, RBC, HGB 9:32 QC passed Normal level 9:28 am failure for WBC, LYM, RBC, HGB, HCT 9:31 am failure for WBC, RBC, HGB, HCT 9:33 am QC passed QC lot #31906, expiration date 10/19/2021 09/29/2019 Low level 11:31 am failure for PLT 12:00 am failure for WBC, LYM, *MID, GRAN, %L, %G, RBC, HGB, HCT, MCV, MCH, RDW, PLT QC lot #31906, expiration date 10/19/2021 10/05/2019 Normal level 8:55 am failure for HCT 8:58 am failure for RBC High level 8:53 am failure for WBC, LYM, *MID, GRAN, %L, %G, RBC, HGB, HCT, MCV, MCH, PLT 8:56 am failure for HCT 9:00 am QC passed The laboratory failed to document corrective action for the above QC failures. 3. During an interview on 10/30/2019 at 3:30 pm, the technical consultant confirmed the laboratory failed to document corrective action for QC failures.
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 review of laboratory policy, Cell-Dyn 1800 hematology quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 8 of 8 patients in 2019 (02/2019, 10/2019 random review). Findings: 1. Review of laboratory policy for CBCs revealed: "Quality Control: Frequency: Three levels of CDS 3PD Hematology Control testing will be performed once every 24 hours. Procedure ... 4. Verify that the results are acceptable. NOTE: Out-of-range results are displayed in inverse video on the screen and underlined on the printout with an out-of-range indicator. 5. If results are unacceptable, repeat the run. If the results are still unacceptable, refer to the Operator's Manual Section 11: Quality Control for troubleshooting. 6. After troubleshooting retest the control. If still out of range, call Preferred Biomed for service. 7. Repeat procedure for each control level L, N, and H. If two out of three levels are within patient range testing may be reported. However, all effort should be made to identify the problem with the one level that is out of range. If more than one control level is out of range do not report patient results." 2. Review of Cell-Dyn 1800 hematology quality control (QC) records revealed test system adjustments performed for the following sampling of QC test events in 2019: 02/11/2019 QC low, normal and high level set lot# 31813, expiration date 05/02/2019 Cell-Dyn 1800 Serial #19646AY Low level 8:49 am QC passed 10:45 am failure for WBC, GRAN, %L, %G, HGB 11:31 am failure for %L, %M Normal level 8:50 am failure for LYM, %L, RBC 9:05 am failure for LYM, %L, RBC, HGB, HCT, PLT 10: 42 am failure for WBC, LYM, *MID, GRAN, %L, %G, RBC, HGB, HCT 11:33 am failure for WBC, LYM, *MID, GRAN, %M, %G, RBC, HGB, HCT, MCV, MCH, PLT 11:36 am failure for WBC, %L High Level 8:52 am failure for LYM, %L, %M 10:41 QC passed 11:37 am failure for LYM, %L, %M Review of corrective action stated "machine was having some problems and had to be serviced also did a report on controls not wanting to come in." Review of the laboratory's "INVESTIGATION

	REPORT OF A FAILURE OF QC" revealed: "8. What is the cause of the failed challenge? Changed to new company on controls and it was not coming in on the manufactur [sic] ranges/limits 9. What is the solution to the problem? call PBL for service 10. What action(s) will be taken to prevent a recurrence? they came out replaced Dil syringe Drive/Dil syringe/sample syringe, found a leak & fixed that something to do with Lyse connections, tighted [sic] probe, replaced WBC GAIN Adjusted & RAN all 3 levels & did a 11 RUN Replica within specs low." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (02/08/2019): Patient ID: 56185 10/03/2019 QC low, normal and high level set lot# 31906, expiration date 10/21/2019 Cell-Dyn 1800 Serial #21840AY Low level 9:00 am failure for PLT 9:21 am QC passed Normal level 9:01 am failure for HCT, PLT 9:22 am failure for HCT 9:27 am failure for HCT High level 9:04 am failure for HCT 9:24 am failure for HCT Corrective action was documented as "10/3/19 QCs out, start new set, still out the QC, make a QC failure report and All patient specimens run upstair [sic] 205 machine." The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (10/02/2019): Patient IDs: 61916, 61914, 61913, 61912, 61910, 61905, 61901 3. During an interview on 10/30/2019 at 3:30 pm, the technical coordinator stated that patients are only evaluated on days when there is a QC failure for two or more levels or if they report patients when QC is out. He stated that patients are not evaluated since the last acceptable QC run when test system adjustments are performed, confirming the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on direct observations, review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records, manufacturer's instructions, quality control (QC) records, corrective action logs, patient test reports, and confirmed in interview, the Laboratory Director failed to provide overall management as evidenced by: 1. The laboratory director failed to meet the requirements for the analytical system. Refer to D6007. 2. The laboratory director failed to ensure PT samples are tested as required. Refer to D6016. 3. The laboratory director failed to document corrective actions for 5 of 5 days that included failures in 2018 and 3 of 3 days in 2019. Refer to D6024. 4. The laboratory director failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 8 of 8 patients in 2019 (02/2019, 10/2019 random review). Refer to D6024.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on direct observations, review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records, manufacturer's instructions, quality control (QC) records, maintenance logs, corrective action logs, patient test reports, and confirmed in interview, the laboratory director failed to meet the requirements for the analytical system, as evidenced by: 1. The laboratory failed to follow manufacturer's instructions for staining blood smears for CBC differentials. Refer to D5411, II. 2. The laboratory failed to follow manufacturer's instructions for flags on the CELL-DYN 1800 hematology analyzer for 3 of 40 patients in 2019 (random review 10/12/2019 through 10/30/2019). Refer to D5411, III. 3. The laboratory failed to ensure reagents, QC (quality control) were labeled with new expiration dates according to the manufacturer. Refer to D5415. 4. The laboratory failed to ensure reagents, QC (quality control) did not exceed their expiration dates. Refer to D5417. 5. The laboratory failed to follow manufacturer's instructions for performing weekly and monthly maintenance for 14 of 14 weeks and 1 of 3 months in 2018 (October through December) and 38 of 38 weeks and 5 of 9 months in 2019 (January through September). Refer to D5429. 6. The laboratory failed to test and document for intended reactivity (QC) for QuickLink III stain for CBC (complete blood count) peripheral blood smears for each day of use in 2018 and 2019. Refer to D5473.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) records and staff interview the laboratory director failed to ensure PT samples are tested as required as evidenced by: 1. The laboratory failed to test hematology PT samples in the same manner as it tests patient specimens for 3 of 3 testing events in 2018 (E-1, E-2, E-3) and 2 of 2 (E-1, E-2) testing events in 2019. Refer to D2006.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established

	performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, quality control (QC) records, corrective action logs, patient test reports, and confirmed in interview, the Laboratory Director failed to provide overall management as evidenced by: 1. The laboratory failed to document corrective actions for 5 of 5 days that included failures in 2018 and 3 of 3 days in 2019. Refer to D5781. 2. The laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 8 of 8 patients in 2019 (02/2019, 10/2019 random review). Refer to D5783.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on direct observations, review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records, manufacturer's instructions, quality control (QC) records, maintenance logs, corrective action logs, patient test reports, and confirmed in interview, the Technical Consultant failed to provide technical oversight as evidenced by: 1. The technical consultant failed to provide technical and scientific oversight for the analytical system. Refer to D6036. 2. The technical consultant failed to document corrective actions for 5 of 5 days that included failures in 2018 and 3 of 3 days in 2019. Refer to D6033. 3. The technical consultant failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 8 of 8 patients in 2019 (02/2019, 10/2019 random review). Refer to D6033.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on direct observations, review of laboratory policy, manufacturer's instructions, quality control (QC) records, maintenance logs, corrective action logs, patient test reports, and confirmed in interview, the technical consultant failed to provide technical and scientific oversight for the analytical system, as evidenced by: 1. The laboratory failed to follow manufacturer's instructions for staining blood smears for CBC differentials. Refer to D5411, II. 2. The laboratory failed to follow manufacturer's instructions for flags on the CELL-DYN 1800 hematology analyzer for 3 of 40 patients in 2019 (random review 10/12/2019 through 10/30/2019). Refer to D5411, III. 3. The laboratory failed to ensure reagents, QC (quality control) were labeled with new expiration dates according to the manufacturer. Refer to D5415. 4. The laboratory failed to ensure reagents, QC (quality control) did not exceed their

	expiration dates. Refer to D5417. 5. The laboratory failed to follow manufacturer's instructions for performing weekly and monthly maintenance for 14 of 14 weeks and 1 of 3 months in 2018 (October through December) and 38 of 38 weeks and 5 of 9 months in 2019 (January through September). Refer to D5429. 6. The laboratory failed to test and document for intended reactivity (QC) for QuickLink III stain for CBC (complete blood count) peripheral blood smears for each day of use in 2018 and 2019. Refer to D5473.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control (QC) records, corrective action logs, patient test reports, and confirmed in interview, the Technical Consultant failed to provide technical oversight as evidenced by: 1. The laboratory failed to document corrective actions for 5 of 5 days that included failures in 2018 and 3 of 3 days in 2019. Refer to D5781. 2. The laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 8 of 8 patients in 2019 (02/2019, 10/2019 random review). Refer to D5783.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel files and confirmed in interview the technical consultant failed to evaluate and document the performance 1 of 8 Testing Persons (TP-3) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of the laboratory's personnel policy revealed: "CLIA guidelines require the semiannual assessment of personnel competency during the first year of test performance for Moderate or High Complexity testing. Thereafter, evaluation must be performed at least annually ...Personnel competency must be addressed by the Laboratory Director or Technical Consultant and will be an on-going process at this facility ..." 2. Review of personnel records for TP-3 revealed an initial training assessment was performed on 12/15/2017 and 6 month competency was performed on 05/2018 for CBCs (complete blood count) and throat cultures. There was no documentation of a semiannual performance for CBCs and throat cultures (due 12/15/2018). 3. During an interview on 10/30/2019 at 10:25 am, the technical consultant stated that the competency assessment was started in December of 2018, but the assessment was not completed until January of 2019, confirming the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel records, and confirmed in interview, the technical consultant failed to perform annual personnel competency assessment for 1 of 8 testing persons in 2017 (TP-6) and 7 of 8 testing persons (TP-1, TP-2, TP-4, TP-5, TP-6, TP-7, TP-8) in 2018. Findings: 1. Review of the laboratory's personnel policy revealed: "CLIA guidelines require the semiannual assessment of personnel competency during the first year of test performance for Moderate or High Complexity testing. Thereafter, evaluation must be performed at least annually ... Personnel competency must be addressed by the Laboratory Director or Technical Consultant and will be an on-going process at this facility ..." 2. Review of personnel records revealed annual competency assessment was not performed for the following personnel in 2017 and 2018: 2017: TP-6 2018: TP-1, TP-2, TP-4, TP-5, TP-6, TP-7, TP-8 3. During an interview on 10/30/2019 at 10:25 am, the technical consultant stated that the competency assessment was started in December of 2018, but the assessment was not completed until January of 2019, confirming the above findings.