Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0477059	07/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pediatric Assoc Of North Texas	2020 W State Hwy 114 Suite 300, Grapevine, 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 on 07/31/2019 with Testing Person-1. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 07/31/2019, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.803(a)(b)(c) Successful Participation 493.1403 Moderate Compexity Lab Director An exit conference was held on 07/31/2019 with Testing Person-1, Administrator and the Laboratory Director. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided. CMS form 2567 will be emailed from the Texas Department of State Health Services, Health Facility Compliance Arlington Group.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

	This CONDITION is not met as evidenced by: Based on a review of Centers for Medicare & Medicaid Services (CMS) 155 report, College of American Pathologists (CAP) proficiency testing records and staff interview, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate for the analyte of red blood cell (RBC). Refer to D2130.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services (CMS) 155 report, College of American Pathologists (CAP) proficiency testing (PT) records, and staff interview, the laboratory failed to attain an overall testing event score of at least 80% for the analyte of red blood cell (RBC) resulting in unsatisfactory performance in 2018 (FH1-C) and 2019 (FH1-B). Findings: 1. Review of the CMS-155 report revealed the following scores in hematology for the RBC analyte for 2018 FH1-C and 2019 FH1-B: 2018 FH1-C: RBC 40% 2019 FH1-B: RBC 40% The laboratory failed to achieve passing scores of at least 80% for the above events. 2. Review of the CAP PT records revealed the following scores for the RBC analyte tested on the Cell-Dyn Emerald analyzer: 2018 FH1-C: RBC 40% 2019 FH1-B: RBC 40% 3. During the exit interview on 07/31/19 at 3:15 pm, the laboratory director and testing person-1 confirmed the above findings.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services (CMS) 155 report, College of American Pathologists (CAP) proficiency testing (PT) records, and staff interview, the laboratory failed to achieve satisfactory performance (80% or higher) for the red blood cell (RBC) analyte in two out of three consecutive testing events resulting in unsatisfactory performance in 2018 (FH1-C) and 2019 (FH1-B). Findings: 1. Review of the CMS-155 report revealed the following scores in bacteriology for 2018 (FH1-C) and 2019 (FH1-B). 2018 FH1-C: RBC 40% 2019 FH1-B: RBC 40% The laboratory failed to achieve a passing testing event score of 80% or higher for two out of three consecutive events for the RBC analyte. 2. Review of the CAP PT records revealed the following scores for the RBC analyte tested on the Cell-Dyn Emerald analyzer: 2018 FH1-C: RBC 40% 2019 FH1-B: RBC 40% 3. During the exit interview on 07/31/19 at 3:15 pm, the laboratory director and testing person-1 confirmed the above 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: Review of laboratory policy, quality control (QC) records, corrective action documentation, and confirmed in interview, the laboratory failed to implement a policy for evaluating patient test results in an unacceptable QC run and since last acceptable QC run to determine if results had been affected. Findings: 1. Review of the laboratory's General Guidelines for Controls Procedures revealed the following: "3 levels are run daily. If 2 of 3 levels are in range can run CBCs. If controls do not run, go through troubleshooting and bleach and/or back flush etc. and rerun controls. Document all corrective actions on the troubleshooting log. If 2 of 3 levels do not run successfully, notify all testing personnel of machine shutdown for the day. For review, give lab director all CBC results since the last successful control runs. Corrective action/troubleshooting log will be audited quarterly ..." The policy did not include evaluating patient test results in an unacceptable QC run and since last acceptable QC run. 2. Review of Abbot Cell-Dyn Emerald hematology analyzer QC data and corrective action documentation revealed troubleshooting the laboratory performed for QC test events in October 2018, May through June 2019. There was no documentation for evaluating all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results. Refer to D5783. 3. During an interview on 07/31/2019 at 2:30 pm, testing person-1 stated that the lab director only evaluates patient test results from the last acceptable QC run when all three levels of QC fail, 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, corrective action documentation, and confirmed in interview, the laboratory failed to document all corrective actions taken when QC was not within acceptable limits for 5 of 5 runs in 2018 (random sampling October) and 2 of 2 runs in 2019 (random sampling May-June). Findings: 1. Review of the laboratory's General Guidelines for Controls Procedures revealed the following: "3 levels are run daily. If 2 of 3 levels are in range can run CBCs. If controls do not run, go through troubleshooting and bleach and/or back flush etc. and rerun controls. Document all corrective actions on the troubleshooting log ..." 2. Review of Cell-Dyn Emerald hematology analyzer QC daily reports revealed that the laboratory did not document corrective action taken when QC was not within acceptable limits for the following QC runs: QC Lot# 8239, expiration date 12/14/2018 10/02/2018 high level was tested at: 7:58 am, 7:59 am, and 8:01 am. All three runs resulted in QC failures. 10/19/2018 normal level was tested at 8:35 am, 8:38 am, 8:46 am. All three runs resulted in QC failures. 10/23/2018 high level was tested at 7:53 am and 7:55 am. Both runs resulted in QC failures. 10/26 /2018 low level was tested at 8:01 am resulting in a failure and 8:03 am; normal level was tested at 7:58 am resulting in a failure and 7:59 am; high level was tested at 8:05 am, 8:06 am, and 8:07 am. All three high level runs resulted in QC failures. 10/29 /2018 low level was tested at 6:59 am resulting in a failure and 7:01 am; normal level was tested at 7:02 am resulting in a failure and 7:05 am; high level was tested at 7:09 am resulting in a failure and 7:11 am. QC Lot# 9042, expiration date 05/31/2019 05/04 /2019 low level was tested at 7:47 am, 7:49 am, and 7:54. All three low level runs resulted in QC failures. Normal level was tested at 7:50 am resulting in a failure and 7: 51 am. QC Lot #9126, expiration date 8/23/2019 06/21/2019 low level was tested at 7: 42 am resulting in a failure and 7:43 am; normal level was tested at 7:46 am resulting in a failure and 7:47 am, high level was tested at 7:48 am, 7:49 am, and 7:50 am. All three high level runs resulted in QC failures. Review of corrective action logs revealed there was no documentation of corrective action for QC repeats or analyzer troubleshooting for the above dates and times. 3. During the exit interview on 07/31 /19 at 3:15 pm, testing person-1 confirmed the above findings. This was a repeat deficiency from 10/30/2015.
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, quality control (QC) records, corrective action

documentation, patient records, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results for 3 of 3 patients in 2018 (random sampling 10/2018) and 19 of 19 patients in 2019 (random sampling 05/2019, 06/2019) Findings: 1. Review of the laboratory's General Guidelines for Controls Procedures revealed the following: "3 levels are run daily. If 2 of 3 levels are in range can run CBCs. If controls do not run, go through troubleshooting and bleach and/or back flush etc. and rerun controls. Document all corrective actions on the troubleshooting log. If 2 of 3 levels do not run successfully, notify all testing personnel of machine shutdown for the day. For review, give lab director all CBC results since the last successful control runs. Corrective action /troubleshooting log will be audited quarterly ..." 2. Review of Abbot Cell-Dyn Emerald hematology analyzer QC data and corrective action documentation revealed the troubleshooting the laboratory performed for the following sampling of QC test events in October 2018, May through June 2019. 10/22/2018 QC normal level lot#8239, expiration date 12/14/2018 was run at 08:01 am and resulted in a failure for MCH and platelet (PLT) analytes. QC was repeated at 8:03 am and resulted in a failure for MCH, PLT analytes. QC was repeated at 8:46 and resulted in a failure for RBC, HCT, MCH, and MCHC analytes. Review of the corrective action log for normal and high levels of QC was documented as "Backflush" and "Clean". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (10/18/2018): Patient IDs 53689, 58363 10/30/2018 QC low level lot #8239, expiration date 12/14 /2018 was run at 8:35 am and resulted in a failure for MCH analytes. QC was repeated at 8:37 am and it passed. QC normal level lot#8239, expiration date 12/14/2018 was run at 8:23 am and resulted in a failure for lymphocyte and MCH analytes. QC was repeated at 8:32 am and it passed. QC high level lot#8239, expiration date 12/14/2018 was run at 8:05 am and resulted in a failure for RBC, MCH and PLT analytes. QC was repeated at 8:08 am and resulted in a failure for granulocyte, RBC, MCH and MCHC analytes. QC was repeated at 8:38 am and resulted in a failure for granulocytes and RBC analytes. Review of the corrective action log for all three levels of QC was documented as "Remix control", "Bleach" and "Clean". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (10/29/2018): Patient ID: 58139 10/31/2018 QC normal level lot#8239, expiration date 12/14/2018 was run at 7: 30 am and resulted in a failure for lymphocyte analyte. QC was repeated at 7:57 am and it passed. QC high level lot #8239, expiration date 12/14/2018 was run at 7:39 am and resulted in a failure for RBC analyte. QC was repeated at 7:58 am and it passed. Review of the corrective action log for normal and high levels of QC was documented as "Bleach", "Backflush", "Clean", and "Remix control". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (10/29/2018): Patient ID: 58139 05/03 /2019 QC high level lot #0942, expiration date 05/31/2019 was run at 8:13 am and resulted in a failure for RBC, MCH, and MCHC analytes. QC was repeated at 8:09 and resulted in a failure for RBC, MCH, and MCHC analytes. QC was repeated at 8: 11 am and resulted in a failure for RBC and MCHC analytes. Review of the corrective action log for high level of QC was documented as "Backflush" and "Clean". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (05/02/2019): Patient IDs: 58755, 58465, 58187, 58602 05/07/2019 QC low level lot #0942, expiration date 05/31/2019 was run at 8:13 am and resulted in a failure for HCT analyte. QC was repeated at 8:14 am and it passed. QC normal level lot #0942, expiration date 05/31/2019 was run at 8:17 am and resulted in a failure for PLT

analyte. QC was repeated at 8:18 am and it passed. QC high level lot #0942, expiration date 05/31/2019 was run at 8:05 am and resulted in a failure for RBC, HCT, MCH, MCHC, and PLT analytes. QC was repeated multiple times and resulted in failures. The following are the times and analyte failures: 8:07 am RBC, HCT, MCH, and MCHC 8:08 am RBC, HCT, MCH, MCHC, and PLT 8:19 am RBC, HCT, and MCH 8:21 am RBC, HCT, MCH, MCHC, and PLT 8:22 am RBC, MCH, and MCHC 8:23 am RBC, and PLT 8:24 am RBC 8:27 am RBC 8:29 am and resulted in failures for RBC and RDW Review of the corrective action log for all three levels of QC was documented as "Remix control", "Backflush", "Clean", and "Means reset". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (05/06 /2019): Patient IDs: 53761, 53619, 16211, 58748 05/15/2019 QC low level lot #9126, expiration date 08/23/2019 was run at 7:59 am and resulted in a failure for WBC analyte. QC was repeated at 08:00 am and it passed. QC high level lot #9126, expiration date 08/23/2019 was run at 7:50 am and resulted in a failure for WBC analyte. QC was repeated at 7:57 am and resulted in a failure for RBC analytes. QC was repeated at 7:58 am and resulted in a failure for MID, RBC, and PLT analytes. Review of the corrective action log for low and high levels of QC was documented as "Remix control", "Backflush", and "Clean". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (05/14/2019): Patient ID: 58951 06/05/2019 QC low level lot #9126, expiration date 08/23/2019 was run at 10:05 am and resulted in a failure for lymphocyte analyte. QC was repeated at 10:13 am and it passed. QC normal level lot #9126, expiration date 08/23/2019 was run at 10:15 am and resulted in a failure for RBC analyte. QC was repeated at 10:21 am and resulted in a failure for hemoglobin (HGB) analyte. QC was repeated at 10:24 and it passed. QC high level lot #9126, expiration date 08/23/2019 was run at 10:25 am and resulted in a failure for HGB analyte. QC was repeated at 10:26 am and it passed. Review of the corrective action log for all three levels of QC was documented as "Backflush", "Clean", and "Remix control" by one testing person. Another testing person documented "Backflush", "Clean", and "Bleach". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (06/04/2019): Patient IDs: 58827, 58842, 50010, 56925 06/06/2019 QC high level lot #9126, expiration date 08/23/2019 was run at 08: 01 am and resulted in a failure for RBC, HGB, HCT, MCH, and MCHC analytes. QC was repeated at 8:03 and 8:06 am both resulted in failures for RBC, MCH and MCHC analytes. QC was repeated at 8:13 am and resulted in a failure for RBC analytes. QC was repeated at 8:31 am and resulted in a failure for RBC, HCT, MCH and MCHC analytes. QC was repeated at 8:32 am and resulted in a failure for WBC, granulocyte, and RBC analytes. Review of the corrective action log for high level of QC was documented as "Bleach", "Backflush", "Clean", and "Remix control" by one testing person. Another testing person documented "Means reset". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (06/04/2019): Patient IDs: 58827, 58842, 50010, 56925 06/07/2019 QC normal level lot #9126, expiration date 08/23 /2019 was run at 08:46 am and resulted in a failure for RBC, HCT, and MCHC analytes. QC was repeated at 9:49 am and it passed. QC high level lot #9126, expiration date 08/23/2019 was run at 08:47 am and resulted in a failure for RBC, HGB, HCT, MCH, MCHC and PLT analytes. QC was repeated at 8:56 am and resulted in a failure for RBC analyte. QC was repeated at 8:57 am and resulted in a failure for WBC, MID%, Granulocyte %, RBC, HGB, HCT, MCH, MCHC, and PLT analytes. Review of the corrective action log for high level of QC was documented as "Remix control", "Backflush", and "Clean" by one testing person. Another testing

person documented "probe bleached". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (06/04/2019): Patient IDs: 58827, 58842, 50010, 56925 06/20/2019 QC low level lot #9126, expiration date 08/23/2019 was run at 08: 17 am and resulted in a failure for HCT, MCH, and MCHC analytes. QC was repeated at 8:18 am and it passed. QC normal level lot #9126, expiration date 8/23/2019 was run at 8:10 am and resulted in a failure for RBC, HCT, MCH, and MCHC analytes. QC was repeated multiple times and resulted in failures. The following are the times and analyte failures: 8:11 am lymphocyte %, lymphocyte, RBC, HCT, MCH, MCHC, and PLT 8:19 am RBC, HCT and MCHC 8:20 am MID%, RBC, and HCT 8:21 am RBC, HCT, MCH, and MCHC 8:32 am RBC, HCT and MCHC 8:33 am RBC, HCT, MCH, and MCHC 8:35 am WBC, RBC, HCT, MCH, MCHC, and PLT 8:36 am WBC, RBC, and HCT 8:37 am MID%, RBC, HCT, MCH, and MCHC 8:38 am and 8: 39 am RBC and HCT 8:57 am MID, lymphocyte %, and MID % QC was repeated at 8:58 am and it passed. QC high level lot #9126, expiration date 8/23/2019 was run at 8:12 am and resulted in a failure for MID %, RBC, HCT, MCH, and MCHC analytes. QC was repeated multiple times and resulted in failures. The following are the times and analyte failures: 8:13 am granulocyte %, granulocyte, RBC, HCT, MCH, MCHC and PLT 8:22 am RBC, HCT, MCH, MCHC and PLT 8:24 am granulocyte, RBC, HCT, MCH, MCHC and PLT 8:25 am RBC, HCT, MCH, MCHC and PLT 8:41 am MID %, RBC, and HCT 8:43 am MID %, granulocyte, RBC, HCT, MCH, and MCHC 8:44 am for RBC and PLT 8:46 am granulocyte, RBC, HCT, MCH, MCHC and PLT 8:48 am granulocyte, RBC, HCT, MCH, and MCHC 8:49 am granulocyte, RBC, HCT, MCH, and MCHC 8:50 am RBC, HCT, MCH, and MCHC 8:56 am RBC QC was repeated at 8:59 am and it passed. Review of the corrective action log for high level of QC was documented as "Remix control", "Bleach", "Backflush", "Clean", and "Means reset". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (06/19/2019): Patient IDs: 58868, 58841, 58852, 58886, and 58873 6/24 /2019 QC normal level lot #9126, expiration date 8/23/2019 was run at 8:30 am and resulted in a failure for RBC, HCT, MCH, MCHC, RDW, and PLT analytes. QC was repeated multiple times and resulted in failures. The following are the times and analyte failures: 8:47 am RBC, HCT and RDW 8:48 am MID%, RBC, HCT and MCHC 8:59 am RBC and HCT 9:06 am RBC 9:08 am RBC, HCT, and MCHC 9:20 am MID%, RBC, and HCT 9:23 am RBC, HCT, MCH, and MCHC 9:44 am RBC and PLT 9:48 am lymphocyte %, lymphocyte, and RBC 12:53 pm RBC 12:54 pm lymphocyte %, MID%, lymphocyte, MID, RBC, HCT, MCH, and MCHC 12:55 pm MID%, MID, RBC, HCT, MCH, and MCHC 12:56 pm RBC, HCT, MCH, MCHC, and PLT 12:57 pm RBC, HCT, MCH, MCHC, and PLT 1:21 pm RBC and PLT 1:24 pm lymphocyte and RBC QC high level lot #9126, expiration date 8/23/2019 was run at 8:30 am and resulted in a failure for RBC, HCT, MCH, MCHC, and PLT analytes. QC was repeated multiple times and resulted in failures. The following are the times and analyte failures: 8:51 am RBC, HGB, HCT, and PLT 9:01 am RBC, HCT, MCH, and MCHC 9:25 am RBC, MCH, and MCHC 9:39 am RBC, MCH, and MCHC 9:43 am HGB and MCHC 9:49 am RBC 9:50 am MID% and RBC 9:52 am WBC, MID%, MID, RBC, HGB, MCH, and MCHC 10:02 am RBC, HGB, MCH, and MCHC 10:04 am WBC, MID%, MID, RBC, and MCH 12:58 pm RBC, HCT, MCH, and MCHC 1: 00 pm MID%, MID, RBC, HCT, MCH, and MCHC 1:01 pm RBC, HCT, MCH, MCHC, and PLT 1:02 pm RBC, HCT, MCH, and MCHC Review of the corrective action log for normal and high levels of QC was documented as "Backflush", "Clean", and "Changed Diluent & Cleaner" by one testing person. Another testing person documented "Bleach", "Backflush", "Clean", "blch [sic] probe", and "Means reset". The following patients were not evaluated to ensure accurate and reliable test results

	since the last acceptable QC run with test system adjustments performed (06/21 /2019): Patient ID: 58891 3. During an interview on 07/31/2019 at 2:30 pm, testing person-1 stated that the lab director evaluates all patients since the last acceptable QC run only when all three levels of control fail and not when performing test system adjustments, 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 a review of Centers for Medicare & Medicaid Services (CMS) 155 report, College of American Pathologists (CAP) proficiency testing records, laboratory policy, quality control (QC) records, corrective action documentation, and staff interview, the laboratory director failed to provide overall management and direction as evidenced by: Findings: 1. The laboratory director failed to ensure PT samples were tested as required. Refer to D6016. 2. The laboratory director failed to ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified. This was a repeat deficiency. Refer to D6024.
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 the Centers for Medicare & Medicaid Services (CMS) 155 report, College of American Pathologists (CAP) proficiency testing (PT) records, and staff interview, the laboratory director failed to ensure patient samples were tested as required under Subpart H of this part. The laboratory failed to achieve satisfactory performance (80% or higher) for the red blood cell (RBC) analyte in two out of three consecutive testing events resulting in unsatisfactory performance in 2018 2018 (FH1-C) and 2019 (FH1-B). Refer to D2130.
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, quality control (QC) records, corrective action documentation, and confirmed in interview, the laboratory director failed to ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified. The laboratory failed to document all corrective actions taken when QC was not within acceptable limits. Refer to D5781 (this was a repeat deficiency).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare & Medicaid Services (CMS) 209 form, personnel records and confirmed in interview, the technical consultant (TC) failed to perform annual competencies for 6 of 15 testing personnel (TP-1, TP-2, TP-3, TP-4, TP-7, TP-10) in 2018 and 4 of 15 testing personnel in 2019 (TP-1, TP-2, TP-3, TP-4) and initial competencies for 3 of 15 (TP-5, TP-6, TP-8) testing personnel in 2019 who performed hematology testing. Findings: 1. A review of the laboratory's CMS 209 form revealed the laboratory identified 15 testing personnel. 2. A review of the laboratory's personnel records revealed the annual competency assessments for 2018 and 2019 were performed by someone other than the TC. The following testing personnel had competency assessments performed by TP-1: TP-2 Competency performed: 01/22/2018, 02/04/2019 TP-3 Competency performed: 03/19/2018, 04/04 /2019 TP-4 Competency performed: 04/20/2018, 03/12/2019 TP-7 Competency performed: 02/05/2018 The following testing personnel had competency assessments performed by TP-15: TP-10 Competency performed: 1/23/2018 3. A review of the laboratory's personnel records revealed the initial competency assessments for 2019 were performed by someone other than the TC. The following testing personnel had competency assessments performed by TP-1: TP-5 Initial competency performed: 03 /07/2019 TP-6 Initial competency performed: 04/30/2019 TP-8 Initial competency performed: 12/14/2018 4. A review of the laboratory's personnel records revealed the annual competency assessments for 2018 and 2019 were not performed by the TC. The following testing personnel had competency assessments performed but was not signed by the technical consultant: TP-1 Competency performed: 02/09/2018, 02/20 /2019 5. A review of the personnel records for TP-1 and TP-15 revealed they did not have documentation of education to qualify as a technical consultant. 6. During an interview on 7/31/19 at 10:20 am, TP-1 stated that she performed the competencies along with the TC. There was no documentation of the TC performing competency assessments on the 9 testing personnel, confirming the above findings.