Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1016874	03/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Chris Burling Md, Pa	618 N Jefferson Suite 1, Mount Pleasant, TX	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records from 2020 to 2022 and confirmed in interview, the laboratory failed to follow the manufacturer's instructions and ensure four of four testing personnel were trained for Covid testing on the Abbott ID Now. The findings were: 1. Review of the package insert for the Abbott ID NOW (INI90000 Rev 4 2020/06) under conditions of authorization revealed "all operators using your product must be appropriately trained in performing and interpreting the results of your product." 2. Review of the laboratory's personnel records available revealed no documentation of training for the Covid testing on the Abbott ID Now per the manufacturer's instructions for four of four testing personnel (TP#1, TP #2, TP#3, TP#4) 3. Review of the CMS116 revealed the laboratory performed 7253 waived testing annually. 4. An interview with the laboratory director on 3/9/22 at 1345 hours in the break room confirmed the above findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including

	instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on review of laboratory procedure, maintenance records, and confirmed in interview, the laboratory failed to retain documentation of maintenance procedures for 2020 and 2021 for the Medonic M Series Hematology Analyzer. The findings include: 1. Review of the laboratory procedure 'Medonic M Series Hematology Analyzer' signed by the laboratory director 8/24/2012 section 'Maintenance' stated: "All maintenance should be documented (a maintenance log is recommended), and the documentation saved for a minimum of 2 years." 2. On 3/9/2022 at 14:45 hours in the laboratory, the surveyor queried for the maintenance records for 2020 and 2021, no such documentation was provided. 3. In an interview on 3/9/2022 at 14:45 hours in the laboratory, testing person 1 stated that they only started recording the maintenance on the maintenance log earlier that month, March 2022, and that there wasn't previous recorded maintenance documentation for the Medonic M Series Hematology analyzer. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records from 2020 and 2021, laboratory records from 2020 to 2022 and confirmed in interview, the laboratory failed to establish quality assessment procedures to ensure the laboratory had a mechanism to monitor, assess, and correct problems in the general lab systems. (proficiency testing) Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records for 2020 and 2021 revealed one of six events when the laboratory failed to attain an acceptable score (> 80%) for the analyte MPV 2021 API 2nd event 40% HSY-07: lab result 7.3 (acceptable range 7.5 - 9.4) HSY-09: lab result 9.1 (acceptable range 7.5 - 8.9) HSY-10: lab result 9.2 (acceptable range 7.5 - 8.9) 2. Review of the laboratory records revealed no documentation of the corrective action for the above PT failure. No policy for proficiency testing corrective actions were available for review. 3. An interview with the laboratory director on 3/9/22 at 1545 hours in his office confirmed the above findings.
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: . Based on observation, laboratory policy, patient results, and confirmed in interview, the laboratory failed to have a policy to include acceptable criteria for specimen labeling for in house labs for four of four patients identified. The findings include: 1. In a tour of the laboratory on 3/9/2022 at 13:05 hours, the surveyor observed four patient collection tubes on a rocker above the Medonic M Hematology analyzer with only one patient identifier. 2. Review of the laboratory policy titled "Specimen Handling and Transport", section "In house labs" did not include instructions for proper specimen identifiers and specimen acceptability criteria. 3. The following four patients were ran on the Medonic M Hematology analyzer with only one positive patient identifier on the collection tube: - ID2 - 11231975 - ID2 - 09281960 - ID2 - 09111970 - ID2 - 02251995 4. In an interview on 3/9/2022 at 13:10 hours in the laboratory, the laboratory director confirmed that the laboratory did not have a policy to include acceptable criteria for specimen labeling for in house labs.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: . Based on review of laboratory records, review of the Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to have documentation of specimen date and time receipt into the laboratory for 2020 and 2021. The findings include: 1. On 3/9/2022 at 13:45 hours in the laboratory surveyor queried for documentation of specimen receipt into the laboratory for 2020 and 2021 and no documentation was provided. 2. Review of the CMS 116 section VIII "Non-Waived Testing" lists an estimated annual test volume for the specialty hematology at 13,800 3. in an interview on 3/9/2022 at 13:45 hours in the laboratory, the laboratory director stated that they did not keep records of specimen date and time it of receipt into the laboratory. .
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: . Based on review of quality controls (QC) records, laboratory policy, review of the Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to have a policy to include the assessment of the acceptability of new lot QC for the Medonic M Hematology analyzer for a new lot rollover reviewed in January 2022. 1. Review of the January 2022 QC records lists the following QC rollover on 1/26/2022: Old Lot QC: 2210901, 2210902, 2210903 New Lot QC: 2211101, 2211102, 2211103 2. Surveyor queried on 3/9/2022 at 15:45 hours for a policy for the assessment of acceptability of new lot QC for the Medonic M Hematology Analyzer, and no such policy was provided. 3. Review of the CMS 116 section VIII "Non-Waived Testing" lists an estimated annual test volume for the specialty hematology at 13,800. 4. In an interview on 3/9/2022 at 15:50 in the laboratory director's office, the laboratory director confirmed that there was no policy for the assessment of acceptability for new lot QC for the Medonic M Hematology Analyzer. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: . Review of laboratory policy, laboratory documents, and confirmed interview, the laboratory failed to perform calibration in February 2022 to fulfil the 6-month requirement for the Medonic M Hematology Analyzer from January 2021 to February 2022. 1. Review of the laboratory policy titled "Medonic M Series Hematology Analyzer" section "Calibration": "Calibration must be performed upon setup of the instrument and then at a minimum of every 6 months." 2. Review of laboratory calibration reports for 2021 have the following calibration documentation: 1/22/2021 6/23/2021 7/30/2021 3. Surveyor queried for the calibration records for February 2022, and no documentation was provided. 4. In an interview on 3/9/2022 at 15:30 hours, in the laboratory director's office, the laboratory director confirmed that calibration was not performed in February 2022 for the Medonic M Hematology Analyzer. .
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 records, review of the Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to document corrective action when QC failed for 21 of 21 days with failures for the months of May and July 2021, and January 2022. 1. Review of laboratory policy for quality control titled "Daily Decisions for Testing Requiring 3 Control Levels" section 1.1.4 stated: "All control values that fall outside +/- 2SD, or that cause a run to be rejected must be documents. This documentation must also include corrective action measures taken." 2. Review of the QC records lists the following 21 days that have QC failures with no documented corrective action for resolution: May 2021: 5 days 5/14/2021 - QC 2210231: 96H - PLT 5/18/2021 - QC 2210231: 100H - PLT 5/20/2021 - QC 2210232: - 4.53H - RBC - 12.8H - HGB - 11.0 H - WBC - 06.1H - LYM - 38.1L - MID - 55.4H - GRA% 5/27/2021 - QC 2210231: 107H / 98H - PLT 5/28/2021 - QC 2210231: 100H - PLT July: 15 Days 7/1/2021 - QC 2210503 - No results/no repeat for WBC, LYM, MID, GRAN, LYM%, MID%, GRA% 7/05/2021 - QC 2210501 - 104H - PLT 7/07/2021 - QC 2210503 430/438 /454L - PLT 7/09/2021 - QC 2210503: 434L / 441L - PLT 7/12/2021 - QC 2210501: 97H - PLT 7/12/2021 - QC 2210503: 452L - PLT 7/15/2021 - QC 2210503: 447L / 449L - PLT 7/19/2021 - QC 2210501: 104H - PLT 7/21/2021 - QC 2210501: 97H - PLT 7/26/2021 - QC 2210501: 110H - PLT 7/26/2021 - QC 2210503: 16.5H - HGB 7 /27/2021 - QC 2210501: 105H - PLT 7/29/2021 - QC 2210501: 99H - PLT 7/29/2021 - QC 2210502: 264H - PLT 7/30/2021 - QC 2210501: 98H - PLT January 202: 1 Day 1/24/2022 - QC 2210903: 99.6H - MCV 3. Review of the CMS 116 section VIII "Non-Waived Testing" lists an estimated annual test volume for the specialty hematology at 13,800. 4. In an interview on 3/9/2022 at 14:40 hours, in the laboratory, TP1 confirmed that the laboratory did not document corrective actions for QC failures that needed corrective action. Key: SD - Standard deviation PLT - Platelet HGB - Hemoglobin RBC - Red blood cell WBC - White Blood Cell LYM - Lymphocyte MID - WBC other than LYM and GRAN GRAN - Granulocyte MCV - Mean corpuscular volume .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records from 2020 to 2022 and

	confirmed in interview, the laboratory director failed to ensure four of four testing personnel had documentation of training for one of one moderate complex testing in hematology (Medonic M series) prior to testing patients' specimens. The findings were: 1. Review of the CMS 209 revealed four testing persons who performed nonwaived testing. 2. Review of the laboratory's personnel records available revealed no documentation of training for the CBC (complete blood count) testing on the Medonic M Series hematology analyzer for four of four testing personnel (TP#1, TP #2, TP#3, TP#4) 3. An interview with the laboratory director on 3/9/22 at 1345 hours in the break room confirmed 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 the CMS form 209, personnel records from 2020 to 2022 and confirmed in interview, the Technical Consultant failed to perform the annual competency evaluations for one of four testing personnel (TP#1). Findings were: 1. Review of the CMS form 209 revealed the laboratory had four testing personnel. 2. Review of the competency assessments for one of four testing personnel (TP#1, hire date 2/19/18) had competency performed on 6/28/21; 12/28/20, and 6/29/20 by TP #1. Testing person #1 has an associates degree. No other documentation was provided to qualify her as a technical consultant. 3. An interview with the laboratory director on 3 /9/22 at 1345 hours in the break room confirmed the above findings. key: CMS - Centers for Medicaid and Medicare Services