Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0214196	03/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Harford Primary Care Llc	615 West Mac Phail Road Suite 106, Bel Air, MD	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: CORRECTED CITATION. DISREGARD COMAR 10.10.06B(6)(a) Quality Control - Single-Use Test Devices. Quantitative Test Systems. SHOULD BE 10.10.06B(6)(b) Quality Control - Single-Use Test Devices. Qualitative Test Systems. Based on record review and interview with laboratory staff, the laboratory was not in compliance with Maryland regulations COMAR 10.10.06B(6)(a) Quality Control - Single-Use Test Devices. Quantitative Test Systems: A licensee shall ensure that quality control testing for a quantitative test system is performed and documented using at least two levels of control material: (i) On each lot of a single-use test device received in a shipment; (ii) At least weekly for each lot of a single-use test device used for patient testing; (iii) After the test system undergoes maintenance, repair, adjustment, or an environmental exposure that could affect the accuracy and reliability of test results. Findings: 1. The "Quidel QuickVue+ hCG[human chorionic gonadotropin] Log" (serum pregnancy) worksheets from 2021 through 2023 were reviewed. 2. On the following dates patients were tested and reported without documentation of two levels of QC being tested: June 13 & 15, 2022, July 27, 2022, August 8 & 31, 2022, September 9 & 30, 2022, October 10, 12, & 27, 2022, November 4, 2022, December 1, 5, 14, & 30, 2022, January 12, 2023, and February 8, 14, & 20, 2023. 3. During the survey on 03/01/2023 at 2:10 PM, the TC confirmed that the laboratory did not comply with COMAR 10.10.06B(6)(a) and perform weekly external quality control each week patient tests are performed. Based on record review and interview with laboratory staff, the laboratory was not in compliance with Maryland regulations COMAR 10.10.06B(6)(b) Quality Control - Single-Use Test Devices. Qualitative Test Systems: A licensee shall ensure that quality control testing for a qualitative test

	system is performed and documented using known positive and negative control materials before patient testing: (i) On each lot of a single-use test device received in a shipment; (ii) At least weekly for each lot of a single-use test device used for patient testing; (iii) After a single-use test device is exposed to an environment or condition that could affect the accuracy or reliability of test results; and (iv) Each day of use during test system validation. Findings: 1. The "Quidel QuickVue+ hCG[human chorionic gonadotropin] Log" (serum pregnancy) worksheets from 2021 through 2023 were reviewed. 2. On the following dates patients were tested and reported without documentation of two levels of QC being tested: June 13 & 15, 2022, July 27, 2022, August 8 & 31, 2022, September 9 & 30, 2022, October 10, 12, & 27, 2022, November 4, 2022, December 1, 5, 14, & 30, 2022, January 12, 2023, and February 8, 14, & 20, 2023. 3. During the survey on 03/01/2023 at 2:10 PM, the TC confirmed that the laboratory did not comply with COMAR 10.10.06B(6)(a) and perform weekly external quality control each week patient tests are performed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of temperature worksheets and interview with the technical consultant (TC), the laboratory failed to define and monitor the acceptable humidity limits for the analyzers used in the laboratory to ensure accuracy and reliability of the test system operation. Findings: 1. The temperature worksheets from August 2021 through February 2023 were reviewed. The worksheets did not include documentation of the humidity. 2. During the survey on 03/01/2023 at 2:10 PM, the TC confirmed that the laboratory had not defined the acceptable humidity requirements for the analyzers and was not monitoring the humidity of the room where the analyzers were being used.
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 observation and interview with the technical consultant (TC), the laboratory failed to label the staining container with the lot number and expiration date of the stain contained within. Findings: 1. The laboratory used a Wright stain for performing manual differential evaluations. 2. The container filled with the Wright stain was not

	labeled with the lot number and expiration date of the Wright stain material contained within. 3. During the survey on 03/01/2023 at 2:15 PM, the TC confirmed that the Wright stain container was not labeled with the lot number and expiration date of the Wright stain in use.
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 observation, record review, and interview with the technical consultant (TC), the laboratory failed to document the staining lot in use and was using expired staining reagent. Findings: 1. The laboratory used a Wright stain for performing manual differential evaluations. 2. The worksheet documenting stain quality control did not indicate which lot of Wright stain was in use and there was no documentation indicating the usage dates for each lot number of Wright stain. 3. During a tour of the laboratory it was discovered that the lot of Wright stain (lot number 1040) that was currently in use expired on 05/04/2022. 4. During the survey on 03/01/2023 at 2:15 PM, the TC confirmed that the lot number of Wright stain currently in use was expired and the laboratory did not document dates of use for Wright stain reagents.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration records and interview with the technical consultant (TC), calibration verification of the hemoglobin A1c (HbA1c) analyzer was not performed at least every six months. Findings: 1. The laboratory used a Bio-Rad D-10

	analyzer to test patient specimens for HbA1c. 2. Calibration records showed that linearity was performed on 06/09/2021, 07/13/2022, and 01/31/2023. 3. Records were missing for the linearity performed around 12/2021. 4. During the survey on 03/01 /2023 at 1:50 PM, the TC confirmed that records for the linearity performed around 12 /2021 were missing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the "Quidel QuickVue+ hCG[human chorionic gonadotropin] Log" (serum pregnancy worksheets) and interview with the technical consultant (TC), the laboratory failed to perform two levels of quality control (QC) each day of testing as required in paragraph (d)(3) of this section and establish an Individualized Quality Control Plan (IQCP) for testing serum pregnancy. Findings: 1. The laboratory is required to test two levels of QC materials each day of testing unless they have written an IQCP. An IQCP plan requires the laboratory to perform a risk assessment that included an evaluation of the specimen used; environment for testing; integrity of the reagent; components of the test system; and competency of the testing personnel. The quality assessment portion of the IQCP should include a review of the QC, proficiency testing records, patient results and all other records pertaining to the serum pregnancy testing. 2. During the survey on 03/01/2023 at 2:10 PM, the TC confirmed that the laboratory did not have an establish IQCP for performing serum pregnancy testing to reduce the frequency of testing QC materials from daily to each shipment.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the "Quidel QuickVue+ hCG[human chorionic gonadotropin] Log" and interview with the technical consultant (TC), the laboratory failed to perform two levels of quality controls (QC) each day of patient testing for the hCG (serum pregnancy test). Findings: 1. The laboratory is open 5 days a week and the TC confirmed that the lab has been performing serum pregnancy testing since the last CLIA recertification survey conducted on 07/29/2021. 2. The serum pregnancy logs

	for 2021 through 2023 were reviewed. There were no QC and patient logs available prior to 06/06/2022. 3. On the following dates patients were tested and reported without documentation of two levels of QC being tested: June 13 & 15, 2022, July 20, 21, & 27, 2022, August 8 & 31, 2022, September 9, 28, & 30, 2022, October 10, 12, 14, & 27, 2022, November 4 & 17, 2022, December 1, 5, 14, & 30, 2022, January 12, 2023, and February 8, 14, & 20, 2023. 4. During the survey on 03/01/2023 at 2:10 PM, the TC confirmed that two levels of QC were not being tested each day of patient testing and there were no QC and patient logs available prior to 06/06/2022.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the standard operating procedures (SOP), record review, and interview with the technical consultant (TC), the laboratory director failed to ensure that the laboratory had a written quality assessment (QA) program to evaluate the ongoing status of the operation of the laboratory. Findings: 1. The SOP that was reviewed had no written QA policies and procedures describing what records are reviewed on a routine basis and how to document the review for the pre-analytical, analytical, and post analytical portions of the laboratory. 2. The TC provided monthly QA reviews for the months of November 2022 through February 2023. There were no records available at the time of the survey showing that a monthly QA review had been performed from August 2021 through October 2022. 3. During the survey on 03 /01/2023 at 2:10 PM, the TC confirmed that the SOP did not include a QA program describing what activities were performed by the TC and shared with the laboratory director and how to document the monthly reviews.
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 competency assessment records and interview with the current technical consultant (TC), the previous TC failed to perform a six month competency assessment for new testing personnel (TP). Findings: 1. The current TC started at the laboratory as TP in 11/2021. 2. The current TC was missing documentation of a competency assessment performed on TP responsibilities six months after hired as TP in 11/2021. 3. During the survey on 03/01/2023 at 2:15 PM, the current TC confirmed that a six month competency assessment was not performed for TP responsibilities.
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 competency assessment records and interview with the current technical consultant (TC), the annual competency assessment records failed to document when or how the competency was assessed. Findings: 1. The document titled "Yearly Competency Assessment for Lab Techs" was used to document annual competency assessments for testing person 1 (TP1) in 2021 and 2022. 2. The form included a space for the testing person's name, the evaluation year, and the evaluator's name. It then listed all six elements used to evaluate competency and a section to document whether the TP passed, failed, or needed improvement. 3. The forms for TP1 had check marks next to each of the six elements and next to "Pass." There was no documentation of when observations took place and what was observed, what documents were reviewed, and how problem solving skills were assessed. There was no date listed as to when the competency assessment was completed and no signature of approval from the evaluator (who was the TC). 4. During the survey on 03/01/2023 at 2:15 PM, the current TC confirmed that the "Yearly Competency Assessment for Lab Techs" forms for TP1 were missing documentation of when and how competency was assessed.