Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1037774	04/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Horizon Internal Medicine	1380 Eastchester Dr, Suite 105, High Point, NC	

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
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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of manufacturer's package inserts, review of 2023, 2024 and 2025 calibration records, and interview with testing personal (TP) #1 on 04/17/25, the laboratory failed to retain documentation of calibrations for the Sensitive Estradiol (SNSE2), Luteinizing Hormone (LH) and Dehydroepiandrosterone Sulfate (DHEA-S) testing performed on the Access 2 analyzer. Findings: Review of manufacturer's package inserts for SNSE2, LH and DHEA-S testing revealed calibrations are required to be performed every 28 days. Review of 2023, 2024 and 2025 calibration records for SNSE2, LH and DHEA-S testing revealed the following: 1. SNSE2, Lot # 272206, calibration expired on 05/15/23, there was no documentation of calibration until 06/12/23. 2. LH, Lot # 338139, calibration expired on 10/06/23, there was no documentation of calibration until 11/03/23. 3. DHEA-S, Lot # 439360, calibration expired on 11/12/24, there was no documentation of calibration until 12/05/24. Interview with TP #1 at approximately 1:15 p.m. confirmed the laboratory failed to retain documentation of the calibrations. TP #1 stated the Access 2 analyzer does not allow you to perform testing if calibrations are expired and they must have misplaced the documentation of the calibrations.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 surveyor observations and interview with TP #1 on 04/17/25, the laboratory failed to ensure expired reagents were not available for use. Findings: At approximately 2:30 p.m. surveyor observed the following expired reagents in the laboratory refrigerator: 1. One box of "Natrol FLU/RSV/SARS-COV-2 Negative Control", Lot # 331569, expiration date 07/31/24. 2. One box of "Natrol FLU/RSV /SARS-COV-2 Positive Control", Lot # 330992, expiration date 05/08/24. 3. One "BUN Flex Reagent Cartridge", Lot # FA4325, expiration date 11/20/24. 4. One "BUN Flex Reagent Cartridge", Lot # BB5008, expiration date 01/08/25. At approximately 3:00 p.m. surveyor observed the following expired reagents in the laboratory freezer: 1. One box of "Access Prolactin Calibrators", Lot # 43913, expiration date 02/28/25. Interview with TP #1 at approximately 3:15 p.m. confirmed the reagents were expired. The reagents were disposed of at time of discovery. This deficiency was cited on the previous survey 9/27/22.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 review of operator's manual and review of 2023, 2024 and 2025 maintenance logs 04/17/25, the laboratory failed to perform and/or document weekly maintenance on the Access 2 analyzer approximately 3 of 52 weeks in 2023 and 1 of 52 weeks in 2024. Findings: Review of operator's manual for the Access 2 analyzer page 6-5 revealed "Weekly Maintenance...In order to keep the Access 2 system running properly, perform weekly maintenance once every seven days." Page 6-6 revealed the following weekly maintenance steps; "Clean Instrument Exterior, Inspect the Liquid Waste Bottle for Wear, Check for Fluid in the Waste Bottle, Inspect and Clean the Primary Probe, Replace and Clean the Aspirate Probes, Run Daily Maintenance, Run Systems Check...Initial Maintenance Log". Review of 2023 and 2024 Access 2 maintenance logs revealed the following weeks in which weekly maintenance was not performed and/or documented: 1. Weekly maintenance was performed 04/10/23 and not performed again until 04/24/23, a period of approximately 14 days. 2. Weekly maintenance was performed 05/01/23, and not performed again until 05/22/23, a period of approximately 21 days. 3. Weekly maintenance was performed 08/21/24, and not performed again until 09/09/24, a period of approximately 21 days.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 the laboratory's policies and procedures, review of 2023, 2024, and 2025 Bio-Rad D-10 records, and interview with the technical consultant (TC) 4/17/25, the laboratory failed to perform and document calibration verification for the Hemoglobin A1c testing performed on the Bio-Rad D-10 analyzer at least once every 6 months. Findings: Review of the laboratory's Bio-Rad D-10 procedure for Hemoglobin A1c testing revealed " ... Calibration Calibration must be performed once, following the installation and priming of every new analytical cartridge. Additional calibration may be performed at the discretion of the laboratory. ..." The procedure describes the use of two calibrators: HbA1c Calibrator Level 1 and HbA1c Calibrator Level 2. Review of the laboratory's "Quality Control Policy" revealed on page 4 "... Calibration and Calibration Verification ... Calibration Verification will be performed at least every six months for those tests which are not routinely calibrated with a minimum of 3 levels of calibration material. ..." Review of 2023, 2024, and 2025 Bio-Rad D-10 records revealed no documentation of calibration verification. During interview at approximately 2:25 p.m., the TC confirmed that the laboratory routinely uses only two levels of calibrator to calibrate the Bio-Rad D-10 analyzer. The TC stated they did not perform calibration verification during 2023 and 2024, and they have not performed it yet in 2025.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of personnel records, review of the laboratory's quality assessment plan, review of 2023, 2024, and 2025 quality assessment records, and interview with the technical consultant (TC) 4/17/25, the laboratory director failed to ensure the quality assessment program was utilized effectively to identify and correct problems and prevent their recurrence. Findings: Review of personnel records revealed the laboratory delegated "the responsibility for Quality Assessment, Quality Control, Policy and Procedure Manual, and Proficiency Testing review to the laboratory Technical Consultant/Supervisor" effective 12/1/22. Review of the laboratory's quality assessment plan revealed "... Key aspects of service are ultimately identified through either employee recognition of recurring problems identified (to include pre and post analytical information), department Action Logs (to include analytical information),

	maintenance logs, quality control logs and at least 6 internal audits per year in which recurring problems have been identified through these monitoring processes. ... Additionally, the technical consultant will review all systems within the laboratory on a monthly basis. ... Expired reagents will be discarded. ... Quality controls are run according to CLIA requirements. If patients are tested with controls not acceptable, a patient remediation chart audit may be done if deemed necessary. ... Quality Control requirements are designated and written for each procedure within the lab. ... Occasionally upon review by the Technical Consultant or Director, these limits may not be met or problems encountered. ... Steps to follow when QC is out of limits are usually listed for each procedure. Having exhausted these suggestions, the supervisor or consultant will launch an extensive investigation including, but not limited to the following. ... 6. Check QC records for trends, shifts, etc. After problem has been identified, corrective action must follow. ... QC monthly review by the consultant should be used as a tool to flag problems involving accuracy of results. ... Patient results will not be reported unless all quality control is within acceptable limits. ...". The quality assessment plan also included a "QUALITY ASSURANCE MONITORING SCHEDULE" which listed reviews/activities to be conducted each month. Review of the laboratory's 2023, 2024, and 2025 quality assessment records revealed the quality assessment program failed to identify the following issues identified during the survey: 1. Calibration records that were not retained (see D3031); 2. Expired reagents that were not discarded and were available for use (see D5417); 3. Weekly maintenance that was not performed as required (see D5429); 4. Calibration verification that was not performed as required (see D5439). Review of the laboratory's 2023, 2024, and 2025 quality assessment records revealed the laboratory failed to conduct patient reviews to ensure patients were not affected on days when quality control was outside the acceptable limits and patients were tested. Examples: a. 10/10/23 quality assessment review noted "QC out" on the following dates when patients tested "DHES - 9/8... Insulin 9/18 ... SNSE2 - 9/25, 9/27 ... Testo - 9/25". There was no documentation of patient review (lookback) on any of the days. b. 1/18/24 quality assessment review noted a "couple of issues" during December 2023. For example, patients were tested on 12/15/23 when one level of Testosterone quality control was outside acceptable limits, and on 12/21/23 when one level of SNSE2 quality control was outside acceptable limits. There was no documentation of patient review on either day. c. 2/29/24 quality assessment review noted "See Jan Review sheets". January 2024 "Review Sheets" showed patients were tested on 1/3 /24, 1/5/24, and 1/25/24 when one level of Testosterone quality control was outside acceptable limits. January 2024 "Review Sheets" also showed patients were tested on 1 /5/24, 1/18/24, and 1/22/24 when one level of SNSE2 quality control was outside acceptable limits. There was no documentation of patient review on any of the days. During interview at approximately 2:20 p.m., the TC confirmed patient lookbacks were not performed as specified in quality assessment records. During interview at approximately 3:30 p.m., the TC also stated that the laboratory had not performed a "Process Audit" to review patient test reports as specified during 2023, 2024, or 2025. This deficiency was cited on the previous survey 9/27/22.