Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1037774	09/27/2022
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
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 manufacturer's instructions, review of the FDA (Food and Drug Administration) website, and interview with TP (testing personnel) 9/27/22, the laboratory failed to include Fact Sheets with patient Cepheid Xpert Xpress and Abbott BinaxNOW SARS-CoV-2 test results. Findings: 1. Review of manufacturer's Instructions for Use for the Cepheid GeneXpert Xpress SARS-CoV-2/Flu/RSV revealed the "Conditions of Authorization for Laboratory and Patient Care Settings" specify "... Authorized laboratories using your product will include with result reports of the Xpert Xpress SARS-CoV-2/Flu/RSV test, all authorized Fact Sheets. ..." Review of the FDA website revealed a "FACT SHEET FOR PATIENTS" and a "FACT SHEET FOR HEALTHCARE PROVIDERS". 2. Review of manufacturer's Instructions for Use for the Abbott BinaxNOW COVID-19 Ag Card revealed the "Conditions of Authorization for Laboratory and Patient Care Settings" specify "... Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. ..." Review of the FDA website revealed a "FACT SHEET FOR PATIENTS" and a "FACT SHEET FOR HEALTHCARE PROVIDERS". During interview at approximately 11:10 a.m., TP #1 confirmed that the Fact Sheets were not provided with their laboratory's SARS-CoV-2 test results.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination,

	and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2021 CAP (College of American Pathologists) proficiency testing records 9/27/22, the laboratory failed to maintain copies of all proficiency testing records for at least two years from the date of the proficiency testing event for 12 of 12 proficiency testing events reviewed. Findings: Review of the laboratory's "Proficiency Testing" policy revealed on page 2 " ... Submission of Proficiency Testing Results 1. CLIA Laboratory director or designee must sign the result form when testing is complete in the attestation line marked 'director or designee'. 2. All personnel who performed the testing of survey materials must sign the attestation page. 3. A copy of the result form, including the attestation, must be retained in the department for the appropriate amount of time per Retention Policy. ..." Review of 2021 CAP proficiency testing records revealed the laboratory failed to maintain copies of report forms used to record proficiency testing results, instrument printouts, or attestation statements signed by the analyst and the laboratory director for the following events: 1. 2021 C-A event - no report forms, no attestation statement 2. 2021 C-B event - no report forms 3. 2021 C-C event - no report forms, no attestation statement 4. 2021 UDS-A event - no report forms, attestation not signed 5. 2021 UDS-B event - no report forms 6. 2021 GH5-A event - no report forms, no instrument printouts, no attestation statement 7. 2021 GH5-B event - no report forms, no instrument printouts 8. 2021 K-A event - no report forms 9. 2021 K-B event - no report forms 10. 2021 VITD-A event - no instrument printouts 11. 2021 BNP5-A event - no report forms, no instrument printouts, no attestation statement 12. 2021 BNP5-B event - no report forms, no instrument printouts, no attestation statement
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2021 CAP (College of American Pathologists) proficiency testing records, and the absence of accuracy verification records 9/27/22, the laboratory failed to verify the accuracy of the Hemoglobin A1c and BNP (B-type Natriuretic Peptides) testing at least twice a year in 2021. Findings: Review of the laboratory's "Proficiency Testing" policy revealed "Addendum A Actions Laboratories take when a PT Result is Not Graded".

	According to Addendum A, the "Action Required" for ungraded results based on Exception Code 11 includes "Perform and document alternative assessment (Semi-Annual Verification) for the period that commercial PT was not tested to the same level and extent that would have been tested." Review of 2021 CAP proficiency testing records revealed the laboratory was enrolled for Hemoglobin A1c in 2021. Review of proficiency testing records revealed all five samples on both the GH5-A and the GH5-B test events were ungraded based on Exception Code 11 - unable to analyze. In the comments section on the Attestation Statement page for test event GH5-B, the laboratory had noted "Instrument gives high pressure issue when PT is processed, issued notified to Bio Rad. Code 11 probably issue with sample handling /delivery." Review of 2021 CAP proficiency testing records revealed the laboratory was enrolled for BNP. Review of proficiency testing records revealed all five samples on both the BNP5-A and the BNP5-B test events were ungraded based on Exception Code 11 - unable to analyze. There was no documentation of any other activities performed to verify the accuracy of the Hemoglobin A1c and BNP testing in 2021.
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 the laboratory's policies and procedures, review of manufacturers' instructions (MI) and interview with TP (testing personnel) 9/27/22, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual did not include a reporting procedure for SARS-Co-V-2 test results. Review of the laboratory's procedure manual revealed it did not include a written, step-by-step procedure for reporting patient SARS-Co-V-2 test results to state or local public health authorities. Review of manufacturers' Instructions for Use for the Cepheid GeneXpert Xpress SARS-CoV-2/Flu/RSV and the Abbott BinaxNOW COVID-19 Ag Card tests revealed the "Conditions of Authorization for Laboratory and Patient Care Settings" specify laboratories using the tests "... will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. ..." During interview at approximately 11:10 a.m., TP #1 confirmed the laboratory did not have a written procedure describing the reporting process. He stated they report SARS-Co-V-2 results to the state through the electronic

	reporting portal and they also fax them to the local health department. 2. The procedure manual did not include the type and levels of QC reagent used for each analyte tested on the Dimension EXL and Access 2 analyzers. Review of laboratory procedure "Quality Control Policy" revealed under "General QC information ...3. Testing personnel will perform and record QC as indicated in each technical procedure ...5. The type of material used will be specified by the manufacturer of the testing platform. 6. Commercially available material will be used for quality control testing if available." The procedure failed to include the type and levels of QC reagent used for each analyte tested on the Dimension EXL and Access 2 analyzers. Review of MI for analytes tested on the Dimension EXL and Access 2 analyzers revealed the MI did not include the type and levels of QC reagent used. Examples: a. MI for Albumin (ALB) states "Quality Control ...At least once each day, analyze two levels of a Quality Control (QC) material with known albumin concentration." b. MI for Amylase (AMY) states "Quality Control Material ...Commercially available quality control materials." c. MI for Alanine Aminotransferase (ALT) states "Quality Control Material ...Commercially available quality control materials." d. MI for Total Prostate Specific Antigen (TPSA) states "Quality Control ...At least once each day analyze two levels of Quality Control (QC) material with known PSA concentrations." 3. The procedure manual did not include the type and/or levels of calibration reagent used for each analyte tested on the Dimension EXL and Access 2 analyzers. Review of laboratory procedure "Quality Control Policy" revealed under "Calibration and Calibration Verification ...For those tests requiring calibration and/or calibration verification, the procedures are performed as outlined in the manufacturer's instructions." Review of MI for analytes tested on the Dimension EXL and Access 2 analyzers revealed the MI did not include the type and/or levels of calibration reagent used. Examples: a. MI for Ferritin (FERR) under "Calibration" is a list showing levels of calibration reagents available and calibration schemes but the procedure fails to state which levels of calibration reagent or scheme is used by the laboratory. b. MI for Iron (FE) states "Calibrator Material ...IRON Calibrator, Cat. No DC85." c. MI for Total Prostate Specific Antigen (TPSA) under "Calibration" is a list showing levels of calibration reagents available and calibration schemes but the procedure fails to state which levels of calibration reagent or scheme is used by the laboratory. Interview with TP #1 at approximately 11:00 a.m. confirmed the laboratory procedure manual failed to include the type and levels of QC reagent used and the type and/or levels of calibration reagent used for each analyte tested on the Dimension EXL and Access 2 analyzers.
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 manufacturers' instructions, observation, and review of the laboratory's 2022 temperature logs 9/27/22, the laboratory failed to establish an acceptable range for freezer temperature that was consistent with manufacturers'

	instructions for the storage of the Bio-Rad Liquichek Immunoassay Plus Control and the Siemens Dimension EXL LOCI Vitamin D calibrator. Findings: Review of manufacturer's instructions for the Bio-Rad Liquichek Immunoassay Plus Control revealed a specified freezer temperature range of -20 to -70 degrees Celsius for storage. Review of manufacturer's instructions for the Siemens Dimension EXL LOCI Vitamin D calibrator revealed a specified temperature range of -15 to -25 degrees Celsius for storage. During a tour of the laboratory at approximately 3:55 p.m., surveyors observed 1 plastic container of Bio-Rad Liquichek Immunoassay Plus Control and 1 box of Siemens Dimension EXL LOCI Vitamin D calibrator stored in the freezer. Review of the laboratory's 2022 temperature logs revealed an acceptable freezer temperature range of -2 to -25 degrees C which was not consistent with manufacturers' instructions for the items stored there. Review of the laboratory's 2022 temperature logs revealed recorded freezer temperatures consistently warmer than -20 degrees Celsius.
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 and interview with TP (testing personnel) 9/27/22, the laboratory failed to discard supplies that exceeded their expiration dates. Findings: During a tour of the laboratory approximately 3:30-3:50 p.m., the surveyor observed the following expired supplies in the storage area, available for use: 1. In the black refrigerator a. 1 open box of Siemens Dimension Flex Reagent OPI cartridge lot #FA2221, expiration date 2/27/22. 2. In the small white freezer a. 1 box Access Ultrasensitive Insulin Calibrators S0-S5 lot #124534, expiration date 5/31/22; b. 1 container (4 vials) Bio-Rad Liquichek Cardiac Markers Plus Control Level 3 lot #29893, expiration date 11/30/21. 3. In the cabinet a. 1 container Siemens Dimension Heterogeneous Immunoassay Module Chemistry Wash lot #56400215, expiration date 12/21/20; b. 1 container Siemens Dimension Heterogeneous Immunoassay Module Chemistry Wash lot #56400351, expiration date 8/17/22. 4. In the drawer a. 13 Puritan UniTranz-RT Transport System tubes lot #200827, expiration date 2/27/22. During the exit interview at approximately 4:45 p.m., TP #1 stated he was unaware the supplies were expired.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions, observation, and review of the laboratory's 2022 temperature logs 9/27/22, the laboratory failed to take and document corrective action for freezer temperatures outside the manufacturers' specified ranges for storage of the Bio-Rad Liquichek Immunoassay Plus Control and the Siemens

	Dimension EXL LOCI Vitamin D calibrator. Findings: Review of manufacturer's instructions for the Bio-Rad Liquichek Immunoassay Plus Control revealed a specified freezer temperature range of -20 to -70 degrees Celsius for storage. Review of manufacturer's instructions for the Siemens Dimension EXL LOCI Vitamin D calibrator revealed a specified temperature rage of -15 to -25 degrees Celsius for storage. During a tour of the laboratory at approximately 3:55 p.m., surveyors observed 1 plastic container of Bio-Rad Liquichek Immunoassay Plus Control and 1 box of Siemens Dimension EXL LOCI Vitamin D calibrator stored in the freezer. Review of the laboratory's 2022 temperature logs revealed recorded freezer temperatures consistently warmer than -20 degrees Celsius with no corrective action documented. Examples: a. August 22-31, 2022 recorded freezer temperatures recorded were between -9 and -12 degrees Celsius for 7/7 days; b. September 1-26, 2022 recorded freezer temperatures were between -7 degrees Celsius and -13 degrees Celsius for 15/15 days.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of MI, review of validation records, and review of random patient test reports 9/27/22, the patient test reports failed to include the reference range, failed to include the reference range established by the laboratory, or failed to include the correct reference range for all analytes tested. 1. Review of random patient test reports revealed the test report failed to include the reference ranges for Folic Acid, Lactate Dehydrogenase (LDH), Uric Acid and SARS-CoV-2 (COVID-19). Findings: a. Review of patient test reports, MRN #78189 reported 9/19/22 and MRN #59741 reported 9/14/22, revealed no reference range for Folic Acid, LDH and Uric Acid. b. Review of patient test report, MRN# 85570 reported 9/23/22, revealed no reference range for SARS-CoV-2 (COVID-19). 2. Review of laboratory procedure and random patient test reports revealed the test reports failed to include the reference ranges established by the laboratory for all analytes tested. Findings: Review of laboratory procedure "New Method/Instrument Validation" revealed "7. Reference Range - This Lab uses the Manufacturer's suggested reference range (Devine Judgement) .... i. Divine judgment. This is where the laboratory reviews the information submitted by the manufacturer and subjectively verifies that the reference intervals are applicable to the adopting laboratory's patient population and test methods.". Review of random patient test reports, MRN #78189 reported 9/19/22 and MRN #59741 reported 9/14/22, and review of MI revealed the reference ranges on the patient test reports are not the reference ranges established by the laboratory. Examples: a. Blood Urea Nitrogen (BUN), patient test reports reference range is 7 to 20 milligrams per deciliter (mg/dL). MI states "Expected values ...Serum: 7-18 mg/dL ...". b. Calcium (CA), patient test reports reference range is 8.5 to 10.5 mg/dL. MI states "Expected values ...NA.". c. Aspartate Aminotransferase (AST), patient test reports reference range is 5 to 34 units per Liter (U/L). MI states "Expected Values ...Add your laboratory-specific expected values here ....15-37 U/L.". d. Gamma-glutamyl Transferase (GGT), patient test reports reference range for a male, MR# 78189, and a female, MR# 59741, is 5 to 55 U/L. MI states "Expected Values ...Add your laboratory-specific expected values here ...

	Females: 5-55 U/L ...Males: 15-85 U/L.". 3. Review of validation records and random patient test reports revealed the laboratory test report for drug screens failed to include the correct reference range for Amphetamines (AMPH), Barbiturates (BARB), Cocaine (COC), and Opiates (OPI). Findings: a. Validation records revealed drug screen cut-off values for the following: AMPH 300 nanograms per microliter (ng /mL), BARB 200 ng/mL, COC 150 ng/mL, and OPI 300 ng/mL. b. Patient test report, MR# 52796 reported 9/10/22, revealed incorrect reference ranges for AMPH - 0.0 to 1000.0, BARB - 0 to 1000, COC - 0 to 300 and OPI - 0 to 250.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2021 CAP (College of American Pathologists) proficiency testing records 9/27/22, the laboratory director failed to ensure corrective action was taken and documented as needed for all unacceptable proficiency testing results. Review of the laboratory's "Proficiency Testing" policy revealed on pages 2-3 " ... Results of Proficiency Tests 1. When survey results are received in the laboratory, they will be reviewed by TC or MT to review, grade, and the signature/review lines on the result form. 2. If there are reported errors, the survey report will be subjected to: i. Repeat testing ii. Competency review iii. Method evaluation studies iv. Continuing education for appropriate staff v. New policy/procedure implementation as needed vi. Past performance for analyte b. Survey and corrective action forms will be signed by the Lab Director or designee". Review of 2021 CAP proficiency testing records revealed there was no corrective action documented for unacceptable results. Examples: 1. 2021 CAP UDS-A test event when the laboratory scored 80% for Opiate Group; 2. 2021 CAP C-B test event when the laboratory scored 20% for GGT (Gamma Glutyl Transferase).
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of 2021 and 2022 Bio-Rad D-10 quality control records and interview with TP (testing personnel) 9/27/22, the laboratory director failed to ensure that a quality control program was established for the hemoglobin A1c testing performed on the Bio-Rad D-10 analyzer. Review of 2021 and 2022 Bio-Rad D-10

	quality control records revealed the laboratory tested two levels of control material (Level 1 and Level 3) each day of patient testing. Review of quality control records printed from the instrument revealed the printouts did not include the lot number of control material used and the laboratory did not have other records to determine the lot number of quality control material in use at a given time. In addition, the laboratory did not utilize Levy-Jennings or any other method to monitor the performance of each lot number of quality control material for shifts and trends. During interview at approximately 1:15 p.m., TP #1 confirmed the laboratory did not have a system in place to monitor the performance of quality control material on the Bio-Rad D-10 analyzer.
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 laboratory's quality assessment plan and review of 2021 and 2022 laboratory records 9/27/22, the laboratory director failed to ensure that the laboratory's quality assessment plan was effective to identify and correct problems identified during the survey. Findings: Review of the laboratory's "Quality Assurance Program" policy revealed the plan did not include specific details describing how all aspects of the laboratory's preanalytic, analytic, and postanalytic systems are monitored. The plan states "... C. SCOPE OF CARE QA programs are overseen and administrated by laboratory professionals devoted to the improvement of testing quality. The laboratory has a Technical Consultant who coordinates quality activities at the Lab and reports to the Director. Plan to Meet Responsibilities 1. The quality and appropriateness of patient care are monitored and evaluated by the following mechanism: a. Routine collection of information about important aspects of the laboratory operation. b. Periodic assessment of the collected information in order to identify important problems in patient care. 2. When problems in patient care are identified, actions are taken and the effectiveness of the action is evaluated. 3. All action taken and the impact of the action, as appropriate, is documented. 4. The Technical Consultant and/or the Medical Director will evaluate information pertaining to patient care and recommend corrective action." The "Quality Assurance Program" policy included the following items to be evaluated, but did not specify the process for evaluation and the frequency of evaluation for all items, and did not specify how to handle corrective action for any issues identified during evaluation: "D. ASPECTS OF CARE 1. LOST SPECIMENS... 2. LABORATORY ACCIDENTS... 3. QUALITY CONTROL ... 4. PROFICIENCY TESTING ... 5. REAGENTS .... 6. SAFETY ... 7. CLIENT CONCERNS ... 8. CORRECTED REPORTS ... 9. REPORTING OF STAT RESULTS ... 10. CRITICAL VALUES ... 11. INSTRUMENT BACKUP ... 12. RECORD FILING AND STORAGE ..." Review of 2021 and 2022 laboratory records revealed no documentation of quality assessment activity on a regular basis. The laboratory's quality assessment plan failed to identify problems in the following areas identified during the survey: 1. Proficiency testing (see D2015, D5215, D6019) 2. Procedures (see D5403) 3. Test systems, equipment,

	instruments, reagents (see D5413, D5417) 4. Corrective actions (see D5785) 5. Test reports (see D5807) 6. Quality control (see D6020).