Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2313128	(X3) Date Survey Completed 09/24/2025
Name of Provider or Supplier Horizon Health Labs	**Street Address, City, State** 43171 Dalcoma Drive Suite 2, Clinton Township, MI	

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation and interview with the general supervisor (GS) the laboratory failed to label 1 of 1 unknown reagent with its contents. Findings include: 1. On 9/24 /2025 at 9:48 am, during a tour of the laboratory, the surveyor observed a specimen cup filled with fluid labeled with open and expiration dates; however, the contents were not identified. 2. On 9/24/2025 at 9:48 am, an interview was conducted with the GS who identified the contents in the unlabeled specimen cup as Surine (synthetic urine), used for diluting patient samples, and confirmed that the specimen cup was not labeled with the contents.
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 observation and interview with the general supervisor (GS), the laboratory failed to ensure 3 (isopropyl alcohol [2], hydrochloric acid [1]) of 3 reagents were not

	used beyond their expiration dates. Findings include: 1. During a tour of the laboratory conducted on 9/24/2025 at 9:30 am, the surveyor observed the following expired reagents: a. 2 bottles of isopropyl alcohol with an expiration date of 4/12 /2024. b. 1 bottle of hydrochloric acid with an expiration date of 12/17/2020. 2. On 9 /24/2025 at 9:50 am, an interview with the GS confirmed that the expired reagents were available for patient testing.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the general supervisor (GS), the laboratory failed to identify the column used while establishing its verification of performance specifications for quantitative urine toxicology testing for 7 (March 2025 through September 2025) of 7 months. Findings include: 1. A record review of the laboratory's verification of performance specifications data revealed that the instrument column used during the data validation was not identified. 2. The surveyor requested verification of performance specifications data identifying the column used during validation; however, the GS was unable to produce documentation. 3. On 9/24 /2025 at 10:20 am, an interview with the GS confirmed that the column information was not included in the verification of performance specifications data prior to patient testing.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the general supervisor (GS), the laboratory failed to include the test report date for 7 (P1, P2, P3, P4, P5, P6, P7) of 7 patient test reports reviewed. Findings include: 1. A record review of patient test reports revealed 7 test reports without report dates: a. Review of test report for P1 with a collection date of 3/28/2025 did not include a test report date b. Review of test report for P2 with a collection date of 4/14/2025 did not include a test report date c. Review of test report for P3 with a collection date of 5/09/2025 did not include a test report date d. Review of test report for P4 with a collection date of 6/26/2025 did not include a test report date e. Review of test report for P5 with a collection date of 7/02 /2025 did not include a test report date f. Review of test report for P6 with a collection date of 8/06/2025 did not include a test report date g. Review of test report for P7 with a collection date of 9/03/2025 did not include a test report date 2. An interview

	conducted on 9/24/2025 at 2:15 pm with the GS confirmed that the test report dates were not documented on the patient test reports.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview with the general supervisor (GS) and laboratory director (LD), the laboratory failed to employ a qualified Clinical Consultant for 7 (March 2025 through September 2025) of 7 months. Refer to D6135.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3) for the subspecialty of oral pathology, 493.1443(b)(5); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: . Based on record review and interview with the general supervisor (GS) and the laboratory director (LD), the laboratory failed to employ a qualified Clinical Consultant for 7 (March 2025 to September 2025) of 7 months. Findings include: 1. A review of the CMS-209 form revealed that the Clinical Consultant position was not documented. 2. On 9/24/2025 at 12:00 pm, the surveyor asked the GS and LD who would be serving as the Clinical Consultant, and the response was that the current LD would serve in the role. 3. A review of the Laboratory Director's qualifications revealed the following: a. He did not qualify as a Laboratory Director under 493.1443 (b)(1), (2), or (3)(i); he holds a Ph.D. in Education. b. He is not a Doctor of Medicine, Doctor of Osteopathy, or Doctor of Podiatric Medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. 4. An interview on 9/24/2025 at 11:50 am with the LD confirmed he did not meet the qualifications to serve as the Clinical Consultant.