Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2065794	08/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
New Kingdom Healthcare	6452 City West Parkway, Eden Prairie, MN	

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	The New Kingdom Healthcare laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification) survey performed on August 27, 2024. The following standard-level deficiencies were cited: 493.1253 Establishment and verification of performance specifications 493.1289 Analytic Systems Quality Assessment 493.1291 Test report .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete required performance verification (PV) activities for one of one new analyzers implemented by the laboratory in 2024. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:05 a.m. on 08/27/24. 2. An Abbott Afinion 2 analyzer was observed as present and available for use during the tour. The laboratory director approved this replacement analyzer for Hemoglobin A1c (HbA1c) testing on 06/17/24. 3. PV documentation for HbA1c testing on the Afinion 2 analyzer, found in the Validation Studies manual, included an accuracy verification via method comparison. Precision and reportable range PV documentation was not found. The laboratory was unable to provide the

	missing documentation upon request. 4. 209 patient specimens received HbA1c testing since implementation on 06/17/24 through date of survey, 08/27/24 as indicated on the laboratory's HbA1c Patient Logs. See below. Month Patients tested June 38 July 87 August 84 5. In an interview at 2:25 p.m. on 08/27/24, the LD confirmed the above finding. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to follow the Quality Assessment Plan (QAP) in 2023 for one of two Individualized Quality Control Plans (IQCP) developed by the laboratory. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:05 a.m. on 08/27/24. 2. An Abbott Afinion 2 analyzer was observed as present and available for use during the tour. The laboratory performed Hemoglobin A1c (HbA1c) testing using this analyzer. 3. The laboratory implemented the IQCP for Afinion Dx Testing to reduce quality control requirements for HbA1c. The IQCP's QAP indicated the IQCP would be reviewed annually. 4. Documentation of 2023 annual IQCP review was not present in laboratory records. The laboratory was unable to provide documentation of the 2023 IQCP quality assessment review upon request. 5. In an interview at 12:45 p.m. on 08/27/24, the LD confirmed the above finding. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of one Chemistry reference intervals was consistent between a procedure and a patient test report in 2024. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:05 a.m. on 08/27/24. 2. An Abbott Afinion 2 analyzer was observed as present and available for use during the tour. The laboratory performed Hemoglobin A1c (HbA1c) testing using this analyzer. 3. The reference interval listed in the Hemoglobin A1c on the Alere Afinion HbA1c Dx procedure, located in the A1c Validation manual, was not consistent with that included on a patient test report from 05/02/24 as indicated below. Analyte Procedure Report HbA1c 4.8-6.0% 3-5.8% 4. In an interview at 2:20 p.m. on 08/27 /24, the LD confirmed the above finding. .