Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2017946	03/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
National Healthcare Center	2088 Idlewood Road, Suite 6, Tucker, GA	

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	On April 16, 2023 an off site follow-up review was completed. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation during the laboratory tour and staff interview, the laboratory failed to implement and establish proper safety procedures to ensure protection from physical, biochemical and biohazardous materials in the laboratory area. Findings: 1. During the laboratory tour it was observed there was no hand wash sink with running water or a flush eyewash equipment (for emergency use) in the laboratory testing and processing area. 2. The fire extinguisher in the laboratory area was last checked in June 2021. 3. The honeywell eyewash solution, on the wall, expired in July 2022. 4. An interview, with the facility manager and owner, during the lab tour, on 03/09 /2023, at approximately 10:30 A.M, confirmed the absence of a hand wash sink with running water, eyewash equipment, and fire extinguishers NOT checked in 2022 and 2023.
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 Quality Assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities on a monthly basis as stated in their QA policy manual from January to March 2021 and from January to March 2023. Findings: 1. A review of the laboratory QA documents revealed the technical supervisor (TS) did not review and sign monthly quality activity checklists in 2021 and 2023. 2. There were no monthly reviews or signed Room Temperature, Humidity, Eye Wash and Refrigerator logs available, during the time of survey, on 03 /09/2023, for 2021 and 2023. 3. Interviews with the laboratory manager/ owner and TP (#5 CMS 209) on 03/09/2023, at approximately 12:35 pm, in the review room, confirmed no Quality Assurance (QA) activities performed January thru March 2021 and January thru March 2023.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on documents review and interviews with the owner and Testing Personnel (TP), the Lab Director(LD) failed to ensure that Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2021 and 2023 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Standard Operating Procedures (SOP), QA and maintenance logs (Room Temperature, Humidity, Refrigerator and eye wash) review revealed the lab director, who is also the Technical Supervisor (TS), did not review or sign Quality Assurance or maitenance logs in 2021 or 2023. 2. An interview with the laboratory owner and (TP#5 CMS209) in the review room on 03/09/2023, at approximately 12:50 PM, confirmed the LD failed to ensure the implementation of a QA plan and review maintenance records for 2021 or 2023.