Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2184836	04/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
New Day Diagnostics, Llc	6701 Baum Dr, Suite 110, Knoxville, TN	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: ========== Based on review of competency evaluations for two of two testing personnel listed on the Laboratory Personnel Report (CLIA) Form CMS-209 for SARS-CoV-2 Human IgG Antibody testing, review of training and competency policy and upon interview with the CLIA Laboratory Manager, it was determined the laboratory failed to follow the policy for performing and documenting competency. The findings include: 1. Review of testing personnel competency evaluations for SARS-CoV-2 Human IgG antibody testing revealed testing personnel one and two listed on the Form CMS-209 had no 6 month competency evaluations completed within the first 6 months of their employment. 2. Review of Training and Competency policy stated, "The competency evaluation and documentation of the performance of employees is conducted within the first 6 months of their employment during the first year of employment." 3. Interview at approximately 1:00 p.m. April 13, 2022 with the CLIA Laboratory Manager confirmed that laboratory failed to follow policy for performing 6 month competency evaluations on two of two testing personnel within the first 6 months of their employment during the first year of employment. ==========
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 review of the laboratory's Quality Assurance Plan, random patient audit dates, and interview with the CLIA Laboratory Manager, determined the laboratory failed to follow policy for General Laboratory Systems Quality Assessment in 2020 and 2021. The findings include: 1. Review of the laboratory's Quality Assurance Plan stated, "EDP has established and follows written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory system." 2. Review of two of five dates selected for patient tracers revealed test well/position discrepancies documented on the "worklist by accession number" form versus the "Q-Plex SARS CoV-2 Human IgG (4-Plex) Results Summary" for three of 18 patient samples tested on 08.04.2020 and seven of seven patient samples tested on 02.18.2021 indicating the laboratory did not have a process in place for detection and correction of errors between the well position on the worklist by accession number and the well position on the result summary. 3. Interview at approximately 1:00 p.m. April 13, 2022 with the CLIA Laboratory Manager confirmed the laboratory failed to follow the Quality Assurance Plan-General Laboratory Systems Quality Assessment on 08.04.2020 and 02.18.2021. ==========