Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1015619	(X3) Date Survey Completed 06/07/2023
Name of Provider or Supplier Norton Cancer Institute Jeffersonville	**Street Address, City, State** 301 Gordon Gutmann Blvd, Jeffersonville, IN	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain patient test records, and quality control documents from June 2021 through May 4, 2022, and one of eight patient record (PT-1- PT-8) requested for review. Findings Include: 1. Review of "Clinical Laboratory Improvement Amendment (CLIA) Applications for Certification (CMS 116)" signed by the laboratory director on 4/20/2021 and 5/26 /2023, indicated non-waived Chemistry and Hematology testing were being performed in 2021 through 2023. 2. On 6/07/2023 at 12:30pm, upon request for patient records for January 2022, SP-2 (Technical Consultant) stated patient records prior to May 5, 2022, could not be accessed due to a recent security breach. No records for the 1st quarter of year 2022 was provided for review. 3. On 6/07/2023 at 12:45pm, during an interview SP-2 (Technical Consultant) was asked if there was a backup system, Sp-2 did not provide a response. 4. Per patient record request the following patients tested on the Sysmex 1000i and Abbott Alinity C Module analyzers could not be retrieved. PATIENT (PT) TEST DATE ACCESS TO RECORDS PT#1 1 /05/2022 NOT AVAILABLE UPON REQUEST 5. Annual Test Volume for Chemistry is approximately 11,100. 6. Annual Test Volume for Hematology is approximately 7,600.
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 record review and interview, the laboratory director failed to establish a Personnel Competency Assessment policy for two (SP-3 and SP-4) of two testing person(s) and two (SP-2 and SP-5) of two technical consultant(s) to evaluate personnel and consultant competency. Findings Include: 1. Review of "Laboratory Personnel Report (CLIA)", signed by the laboratory director on 6/07/2023 indicated the following: a) SP-2 and SP-5 are Technical Consultants. b) SP-3 and SP-4 are testing person. 2. Upon request for competency assessment policies the following policies were provided: a. "Quality Assurance Monitoring", reviewed by the laboratory director on 3/14/2021. b. "Quality Assurance Plan- Overview", reviewed by the laboratory director on 3/14/2021. c. Neither policy included how competency assessments for testing personnel or technical consultants will be performed or who will perform the competency assessments. 3. On 6/07/2023 at 1:16pm, during an interview with SP-2 (Technical Consultant), SP-2 was asked to provide a policy on competency assessment for testing personnel and consultants. SP-2 stated the policy is in the process of revisions due to a system breach and was not available for review.