

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2309014	(X3) Date Survey Completed 04/23/2025
Name of Provider or Supplier Illinois Cancer Specialists	Street Address, City, State 8915 W Golf Rd, Niles, IL	
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
D5475	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g)</p> <p>(e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the general supervisor (GS); the laboratory failed to document flow cytometry immunophenotyping fluorescent antibody stains for positive and negative reactivity / quality control (QC) each time of use for four of four patients reviewed from the beginning of testing in October 2024 through the date of survey, 04/23/2025. Findings include: 1. Review of laboratory policies and procedures revealed the procedure, "Sample Preparation", which stated, under "Quality Control", "Quality Control in Flow Cytometry Immunophenotyping is accomplished in different ways and at different stages." 2. Review of laboratory records revealed the document, "Monthly Antibodies Positive QC", which indicated the following 30 flow cytometry immunophenotyping fluorescent antibody stains being utilized: CD2 CD22 CD3 CD23 CD4 CD33 CD5 CD34 CD7 CD38 CD8 CD45 CD10 CD56 CD11b CD57 CD11c CD64 CD13 CD103 CD14 CD117 CD15 FMC-7 CD16 HLA-DR CD19 Kappa CD20 Lambda 3. Review of patient testing results for four of four flow cytometry immunophenotyping fluorescent antibody stain testing dates found that no flow cytometry immunophenotyping fluorescent antibody staining positive and negative reactivity / QC was documented for these days of patient testing. Report Date: Specimen ID: 11/05/2024 5979922 01/15/2025 6013927 03/03/2025 6039642 04/17/2025 6064669 4. Upon a tour of the laboratory on 04/23/2025, at 10:23 am, the GS confirmed the laboratory was only running positive reactivity of flow cytometry immunophenotyping fluorescent antibody stains monthly from the beginning of testing in October 2024 through the date of survey, 04/23/2025.</p>