

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2026717	<b>(X3) Date Survey Completed</b>  08/15/2019
<b>Name of Provider or Supplier</b>  Integrated Regional Laboratories Pathology	<b>Street Address, City, State</b>  120 Ne 167th Street, North Miami Beach, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey conducted on 8/15/2019 found that the Integrated Regional Laboratories Pathology clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with staff, the laboratory failed to have annual competency assessment evaluation for 1 out of 2 Clinical Consultant staff (CC) (CC # B); 3 out of 3 testing personnel (TP) (TP# A, TP # B and TP # C) ; during the period of 2 out 2 years reviewed, and for 1 out of 2 General Supervisor (GS) (GS #B); during 1 out of 2 years reviewed. Findings include: Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 8/29/2019 revealed: a) 2 Clinical Consultant (CC) (CC # A was the laboratory Director and CC #B is a TP # C) b) 2 G S (GS # A is the LD and GS # B) c) 3 TP (TP # A, TP # B, TP # C). Review of employee documentation revealed the following: - No annual competency evaluation for CC # B; during the period of 2 out of 2 years reviewed. - TP # A; the forms provided to document the annual competency assessment did not correspond with this facility. 1)Form signed on 10/4/2018, Competency Assessment: RRL Histotechnician/ Histotechnologist with case IRLSS18: 11489. The date of the case was 9/12/2018, as per the patient log, no cases tested on the day of reference at the facility object of this survey. This competency assessment had a review for Cytology which is not listed in the 116 as specialty for this laboratory. 2)Form signed on 10/01 /2018, Employee annual training checklist document as the Facility: IRL Core Histology. -TP # B: The documentation provided did not meet requirements: a)</p>

Competency Assessment for Histology Procedures performed by Histology technologist form, signed on 8/4/2017 and 8/29/2018, the evaluator was a TP # B. b) Form GEN 15A V1 03-13 Annual Competency signed on 12/5/2018, the evaluator listed for the assessment is not included in form 209. Tasks evaluated like patient accessioning, embedding, microtomy, staining, IHC (immunohistochemistry), are not performed at this facility. -TP # C: The documentation provided did not meet the requirements a) Pathologist Professional Practice Evaluation form of HCA Physician Services Group, is a company form provided as annual competency assessment, missing the 6 points required for the testing personnel. The 2017 signed on 3/12/2018 by a Chief Medical Officer not listed on the 209. b) The Initial Professional Practice Evaluation PS200bV2 0617 form signed by the LD on 8/13/2019, listed 3 cases for 2017 and 2 for 2018, no supporting documentation was provided to confirm that the cases reviewed are associated with this facility. -GS # B evaluation signed on 1/10/2019 with a hiring date of 5/1/2018, states Core Histology manager and it is signed by Medical Director IRL, the signing person is not listed on the form CMS 209 as LD, a review of the ASPEN 116 web system, the signing person appears as the LD for laboratory with CLIA number for another facility. During a phone interview with Quality staff, on 08/15/2019 at 12:30 PM, she confirmed that this was the competency assessment they have for the personnel of above-reference.

**D5309**

TEST REQUEST  
CFR(s): 493.1241(e)

If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

This STANDARD is not met as evidenced by:  
Based on the review of patient reports and interview with testing personnel (TP) A at 9:30 AM; the information on the report was inaccurate for 1 out of 3 reports reviewed. Findings include: Review of final reports with case numbers SS18:11555, SS18:13213 and SS18:14476; during the period of 2018, revealed that, report SS18:11555 failed to list the location for the frozen intra-operative consultation. During an interview on 8/15/2019 at 12:30 PM, with the TP, he confirmed that the report did not include the location where they performed the frozen section for the intra-operative consultation