

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2040165	(X3) Date Survey Completed 05/09/2018
Name of Provider or Supplier 21st Century Oncology Llc	Street Address, City, State 1043 Ne 46th Ct, Fort Lauderdale, FL	
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
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to record the Immunohistochemical (IHC) stains for negative reactivity for each IHC stain they performed from 5/9/16 to 5/9/18 Findings included: Review of the log titled "South Florida LLC. Immunohistochemical Quality Control Worksheet 2016", "South Florida LLC. Immunohistochemical Quality Control Worksheet 2017" and "South Florida LLC. Immunohistochemical Quality Control Worksheet 2018" showed the laboratory failed to document a negative control slide for each of the following IHC stains: Actin (Muscle Specific HHF-35 IHC stain), CALP (Calponin 1 Antibody IHC stain) CK7 (Cytokeratin 7 Protein IHC stain), CK20 (Cytokeratin 20 IHC stain), ECAD (E-Cadherin, epithelial cells IHC stain), ER (Estrogen Receptor IHC stain), ERG (Endothelium; Tmprss2-ERG IHC stain), Ki67 (cell proliferation IHC stain), P53 (P53 gene IHC stain), P63 (P63 gene IHC stain), PIN4 (p504S + p63 + HMW Keratins IHC stain), PANK (Pantothenate Kinase IHC stain), PR (Progesterone Receptor IHC stain), and PTEN (Endometrial Carcinoma IHC stain). During an interview on 5/9/18 at 3:45 PM, Laboratory Director confirmed that he didn't record the IHC stained slides for negative reactivity.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p>

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to list address where the professional component was performed. Findings include: Review of the patient reports showed that the address of the laboratory where the professional component was performed was not listed on the patient reports from 5/9/16 to 5/9/18. During an interview on 5/9/18 at 3:40 PM, Laboratory Director stated he did not know that the address where the professional component was performed needed to be on the patient reports.