

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0724226	(X3) Date Survey Completed 07/09/2019
Name of Provider or Supplier Azalea Skin Treatment Center	Street Address, City, State 501 Health Park Drive, Suite 150, Garner, NC	
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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2017, 2018 and 2019 quality control (QC) logs, and review of 2017, 2018 and 2019 Mohs surgery patient logs 7/9 /19, revealed the laboratory failed to document quality control of the Hematoxlin and Eosin (H&E) staining performed by the laboratory. Review of laboratory procedure "Stain Maintenance" revealed, "10. A QC work sheet is documented daily on the stain quality and any corrections or changes made." Review of H&E "Quality Control Staining" logs and review of Mohs surgery patient logs revealed the laboratory failed to document H&E quality control on 11 days from 12/21/17 through 4/17/19. Approximately 87 patients were affected. The dates and number of patients are as follows: 1. 12/21/17 - 6 patients 2. 3/1/18 - 16 patients 3. 5/10/18 - 8 patients 4. 5/17 /18 - 8 patients 5. 5/30/18 - 7 patients 6. 6/7/18 - 6 patients 7. 8/22/18 - 7 patients 8. 8 /23/18 - 7 patients 9. 1/31/19 - 7 patients 10. 2/7/19 - 7 patients 11. 4/17/19 - 8 patients</p>