

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2112314	(X3) Date Survey Completed 01/30/2020
Name of Provider or Supplier Novant Health Cancer Institute Ballantyne	Street Address, City, State 10905 Providence Road West, Charlotte, 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
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's "Lab General Maintenance" policy, review of the 2018, 2019 and 2020 temperature/ humidity logs, and interview with the technical consultant(TC)1/30/2020, the laboratory failed to ensure corrective action was taken and documented for refrigerator readings outside the acceptable limits. Findings: The laboratory's policy states under Temperatures/humidity, "Any temperatures out of range should have corrective action performed and should be documented on the temperature/general maintenance log or corrective action form..." The laboratory began documenting minimum/maximum readings for the laboratory's refrigerator in August 2019. Review of the 2019 and 2020 Temperature/ humidity logs revealed the refrigerator's temperature was outside the acceptable limits of 2-8 degrees Celsius(C) on the following days with no corrective action documented: a. 6 of 19 days in August 2019- 8/6, 8/7, 8/9, 8/12, 8/13, 8/29; b. 5 of 21 days in September 2019-9/16, 9/24, 9/26, 9/27, 9/30; c. 8 of 22 days in October 2019- 10/2, 10/4, 10/8, 10/10, 10/11, 10/14, 10/21, 10/22; d. 7 of 20 days in November 2019- 11/1, 11/6, 11/11, 11/13, 11/14, 11/22, 11/27; e. 13 of 21 days in December 2019- 12/2, 12/3, 12/5, 12/6, 12/9, 12/11, 12/12, 12/13, 12/16, 12/17, 12/19, 12/23, 12/24; f. 3 of 21 days in January 2020- 1/2, 1/9, 1/30. At approximately 1:30pm, the TC confirmed there was no documentation of corrective action for the minimum/maximum readings that were outside the acceptable limits of 2-8 degrees C.</p>