

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2162722	(X3) Date Survey Completed 04/15/2021
Name of Provider or Supplier Integrated Research Diagnostics	Street Address, City, State 6135 Woodward Avenue Room 2221, Detroit, MI	
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD) and Testing Personnel (TP) #1, the laboratory failed to document corrective action for the out of range humidity readings in the laboratory and the storage area for 6 months (February, March, and December in 2020 and January, February, and March 2021) of 2 years of documents reviewed. Findings include: 1. A record review of the "Room 2221 Temperature and Humidity log 207" and "Room 2221 Temperature and Humidity log 117" showed the range for acceptable humidity is 20 - 85%. The logs revealed for 6 months of 2 years reviewed the following dates had humidity readings outside the stated range: A. laboratory log 1. February 2020 - 13, 14, and 20 2. January 2021 - 4-6, 12-15, 19, 21-22, and 25-29 3. February 2021 - 11, 17-18, and 24-26 4. March 2021 - 1-2, 4-5, 8-12, 19, and 22 B. storage area log 1. February 2020 - 3-7, 10-13, 17, 19-21, and 26-28 2. December 2020 - 8, 11, 14-18, and 21-22 3. January 2021 - 4-8, 11-15, 19-22, and 25-29 4. February 2021 - 1-5, 8-12, 15-19, and 22-26 5. March 2021 - 1-2, 4-5, 8-12, 19, and 22 2. An interview on 4/15/2021 at 9:37 am, the LD and TP1 confirmed no corrective action had been performed and documented to resolve the out of range humidity readings.</p>