

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2063353	(X3) Date Survey Completed 10/09/2019
Name of Provider or Supplier B Jeffrey Wallis Md Pa D/B/A	Street Address, City, State 6208 W Corporate Oaks Dr 2nd Fl, Crystal River, 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
D0000	An announced CLIA recertification survey was conducted at B Jeffrey Wallis MD PA dba Advanced Gastroenterology on 10/09/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level 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 staff interview, the laboratory failed to document corrective action when the room temperature was out of range for records reviewed from January 11, 2018 to October 7, 2019. Findings included: Record review of the "Histology Quality Control Log" showed the room temperature range should be "65 - 70 Degrees F (Fahrenheit)." The bottom of the form stated, "Document Corrective Action on the Back of this Form." Record review of the "Histology Quality Control Log" revealed the room temperature was out of range and no corrective action was performed on the following days: 01/11/2018 - 56 degrees F 01/13/2018 - 56 degrees F 02/19/2018 - 72 degrees F 03/18/2018 - 72 degrees F 03/22/2018 - 72 degrees F 04/17/2018 - 72 degrees F 04/20/2018 - 73 degrees F 04/26/2018 - 72 degrees F 05/04/2018 - 73 degrees F 05/09.2018 - 73 degrees F 01/16/2019 - 72 degrees F 02/04/2019</p>

- 75 degrees F 02/18/2019 - 79 degrees F 02/21/2019 - 77 degrees F 02/22/2019 - 77 degrees F 03/03/2019 - 79 degrees F 03/04/2019 - 78 degrees F 03/08/2019 - 79 degrees F 03/11/2019 - 79 degrees F 03/15/2019 - 78 degrees F 03/18/2019 - 79 degrees F 03/22/2019 - 79 degrees F 03/27/2019 - 76 degrees F 03/29/2019 - 78 degrees F 04/02/2019 - 78 degrees F 04/05/2019 - 77 degrees F 04/10/2019 - 76 degrees F 04/12/2019 - 78 degrees F 04/22/2019 - 76 degrees F 04/23/2019 - 76 degrees F 04/29/2019 - 78 degrees F 05/01/2019 - 72 degrees F 05/03/2019 - 72 degrees F 05/08/2019 - 72 degrees F 05/15/2019 - 72 degrees F 05/20/2019 - 78 degrees F 05/21/2019 - 76 degrees F 05/31/2019 - 75 degrees F 06/04/2019 - 78 degrees F 06/12/2019 - 79 degrees F 06/14/2019 - 79 degrees F 06/19/2019 - 74 degrees F 06/21/2019 - 73 degrees F 06/27/2019 - 73 degrees F 06/29/2019 - 76 degrees F 07/08/2019 - 72 degrees F 07/11/2019 - 74 degrees F 07/14/2019 - 76 degrees F 07/18/2019 - 72 degrees F 07/21/2019 - 74 degrees F 07/26/2019 - 72 degrees F 07/29/2019 - 72 degrees F 08/11/2019 - 76 degrees F 08/14/2019 - 75 degrees F 08/20/2019 - 72 degrees F 08/22/2019 - 74 degrees F 08/24/2019 - 73 degrees F 08/29/2019 - 72 degrees F 08/31/2019 - 72 degrees F 09/12/2019 - 74 degrees F 09/16/2019 - 73 degrees F 09/23/2019 - 71 degrees F 09/26/2019 - 71 degrees F 09/30/2019 - 73 degrees F 10/03/2019 - 73 degrees F 10/07/2019 - 72 degrees F Interview on 10/09/2019 at 3:40 PM with the Histology Supervisor confirmed that temperatures were documented outside of the normal range and no corrective action was performed. The Histology Supervisor stated the thermostat was downstairs and because of the windows in the laboratory, the laboratory temperature exceeded the stated range on the "Histology Quality Control Log."