Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2165676	10/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Episcopal San Lucas Ii	Ave Tito Castro # 917, Ponce, PR	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on procedure manual, histopathology quality control records review (years 2018-2019)and pathology laboratory histotechnologist interview at 11:00 AM on October 24, 2019, it was determined that the laboratory failed evaluate and take corrective actions when Fume Absorber air flow measures were not within the established range of 90-120 Fpm. The findings include: 1. The laboratory used the Fume Absorber (AC 6327TA) in the frozen section area since September 18, 2019. 2. The laboratory procedure manual established that the laboratory must monitor and document, each daily of use, the Fume Absorber (AC 6327TA) instrument airflow. (Range 90-120 Fpm). 3. From September 18, 2019 to October 24, 2019, the Fume Absorber (AC 6327TA) air flow records showed that the laboratory documented air flow measurements below 90 Fpm on 12 out of 13 days of use: Date Airflow #'s (Fpm) samples 9/18/19 81 3 9/20/19 83 8 9/23/19 80 1 9/26/19 85 4 9/30/19 80 2 10/2 /19 78 5 10/3/19 80 2 10/7/19 85 2 10/9/19 83 4 10/16/19 NAFR 3 10/17/19 86 3 10 /23/19 84 8 *NAFR = no air flow recorded 5. The laboratory processed and reported forty five (45) frozen sections patient's samples from September 18, 2019 to October 23, 2019. 6. The testing personnel confirmed on October 24, 2019 that the laboratory documented the instrument air flow below 90 Fpm in Fume Absorber (AC 6327TA) and did not take any remedial or corrective actions.
D5028	HISTOPATHOLOGY CFR(s): 493.1219

	If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on procedure manual, histopathology quality control records review (years 2018-2019) and interview with the pathology laboratory 11:00 AM on October 24, 2019, it was determined that the laboratory failed to meet the requirements to provide laboratory services in subspecialty of Histopathology. Refer to: D5781 (the laboratory did not take any corrective action when the cryostat temperatures were not within the established temperature range).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the pathology procedure manual (P-1001- Frozen Section Protocol) frozen section patient's log review , observation and interview with the histotechnologist on October 24, 2019 at 11:00 AM, it was found that the procedure manual did not include written procedures for multiple block frozen sections turn around time. The findings include: 1. Review of the pathology procedure manual , section 3.4, stated that the turn around time on multiple block frozen sections will vary depending on the number of cryostats and cutters available. 2. During the survey the frozen section area was observed, only one cryostat was used for frozen section procedures. 3. Review of the frozen section patient's log showed that 218 out of 336 patient's had more than one block, however the turn around time was not established. 4. The histotechnologist stated that no written procedures for multiple blocks were established.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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.

This STANDARD is not met as evidenced by:
A. Based on histopathology procedure manual, histopathology quality control records review (years 2018-2019) and interview with the pathology laboratory histotechnologist at 11:00 AM on October 24, 2019, it was determined that the laboratory did not take nor document any corrective actions when the cryostat temperature was not within the expected temperature range of minus 20C to minus 30C. The findings include: 1. The laboratory used the Leica Cryostat HESLP (CM1850-3-1) for processing frozen section patient's tissue samples. 2. The laboratory procedure manual established that the laboratory must monitor and document, each day of use, the Leica Cryosta HESLP (CM1850-3-1) instrument temperature. 3. The histopathology laboratory procedure manual (Procedure P & P # : P-1004) - Frozen section protocol; section 7.0 (equipment); 7.1 (Cryostat/Microtome); 7.1.1 showed the following: "The Cryostat will be checked daily by the histotechnologist early in the morning and immediately after a Frozen Section procedure is initially announced for proper temperature and functioning. The temperature has been established at minus 20 C to minus 30 C to cover a wide range of specimens and for easy up and down adjustment within the established range of minus 20 C to minus 30 C". 4.On October 24, 2019 at 11:00 AM the Leica Cryostat HESLP temperature records from March 14, 2018 to February 6, 2019, showed that the laboratory document temperatures outside the expected range of minus 20 C to minus 30C on 98 out of 98 days of sample testing and did not take any remedial or corrective actions: Date C temp C temp #'s Chamber CryoBar samples 3/14/18 -15 -15 2 3/16/18 -15 -15 4 3/19/18 -15 -15 1 3/20/18 -16 -15 1 3/21/18 -17 -15 9 3/23/18 -19 -14 5 3/26/18 -18 -14 1 3/28/18 -17 -14 4 4/4/18 NTR NTR 3 4/6/18 NTR NTR 3 4/9/18 -17 -14 1 4/12/18 -17 -14 3 4/18/18 -17 -14 3 4/25/18 -17 -14 4 4/26/18 -18 -14 1 5/2/18 -14 -10 9 5/9/18 -17 -14 8 5/10/18 -16 -14 10 5/14/18 -13 -14 1 5/18/18 -17 -14 5 5/24/18 -15 -14 3 5/28/18 -17 -15 1 5/29/18 -17 -14 5 5/30/18 -17 -15 5 6/6/18 -14 -13 3 6/7/18 -16 -14 3 6/8/18 -14 -14 2 6/13/18 -16 -16 8 6/14/18 -16 -14 2 6/18 /18 -16 -14 1 6/19/1 -16 -14 2 6/20/1 -17 -14 3 6/21/18 -17 -14 2 6/26/18 -17 -14 2 6 /27/18 -17 -14 9 6/28/18 -17 -15 2 6/29/18 -15 -12 4 7/5/18 -14 -14 3 7/18/18 -17 -13 10 8/1/18 -17 -15 4 8/3/18 -17 -15 8 8/15/18 -16 -15 7 8/17/18 -17 -14 3 8/23/18 -14 -12 2 8/27/18 -16 -13 3 8/29/18 -20 -14 11 9/5/18 -17 -14 3 9/6/18 -16 -14 5 9/7/18 -16 -12 6 9/12/18 -17 -14 6 9/13/18 -17 -14 6 9/14/18 -17 -14 3 9/19/18 NTR NTR 9 9 /20/18 -16 -14 2 9/21/18 -16 -13 2 9/26/18 -17 -14 5 9/27/18 -17 -14 8 9/28/18 -16 -13 13 10/1/18 -17 -12 4 10/3/18 -17 -14 6 10/5/18 -17 -14 6 10/9/18 -17 -14 1 10/10/18 -17 -14 4 10/11/18 -17 -14 5 10/12/18 -17 -14 7 10/17/18 -17 -14 6 10/18/18 -17 -13 4 10/29/18 NTR 33 1 10/30/18 -20 -17 2 10/31/18 -18 -16 8 11/1/18 -18 -14 3 11/2/18 -16 -14 4 11/6/18 -18 -15 2 11/7/18 -16 -15 2 11/9/18 -17 -14 4 11/12/18 -16 -14 4 11 /14/18 -16 -14 3 11/16/18 -18 -14 4 11/27/18 -18 -14 1 11/28/18 -18 -14 9 11/29/18 -17 -14 3 12/5/18 -17 -14 2 12/6/18 -16 -14 1 12/12/18 - 15 -14 9 12/13/18 -17 -14 5 12/14/18 -17 -14 11 12/20/18 -17 -14 4 12/21/18 -17 -14 1 1/2/19 -18 -14 2 1/6/19 -16 -14 2 1/16/19 -16 -14 10 1/18/19 -16 -14 4 1/23/19 -16 -14 3 1/29/19 -18 -14 1 1/30 /19 -18 -14 5 2/4/19 -18 -14 1 2/6/19 -18 -14 12 *NTR =no temperature record 5. The laboratory processed and reported four hundred forty (440) frozen sections patient's

	samples from March 14, 2018 to February 6, 2019. 6. The testing personnel confirmed on October 24, 2019 that the laboratory used the Leika Cyostat outside the expected temperature range and did not take any remedial or corrective actions. B. Based histopathology procedure manual, histopathology quality control records review (years 2018-2019) and interview with pathology laboratory histotechnologist at 10:45 AM on October 24, 2019, it was determined that the laboratory did not take any corrective actiions when tissue processor area room temperature was out of range. The findings include: 1. The laboratory procedure manual established that the laboratory must monitor and document each daily of use the tissue processor area room temperature (18 C to 28C). 2. From March 14, 2018 to October 23, 2019, the room temperature records showed that the laboratory documented temperatures out of the established temperature range (18 C to 28C) in tissue processor area and did not take any remedial or corrective action. 3. The laboratory documented room temperatures below the established range on 43 out of 98 days: Date C temp. #'s samples 3/16/18 13 4 3/19/18 13 1 3/20/18 14 1 3/21/18 14 9 3/23/1 14 5 3/26/18 14 1 3/28/18 14 4 4/4 /18 14 3 4/6/18 14 3 4/9/18 14 1 4/12/18 13 3 4/18/18 13 3 4/25/18 13 4 4/26/18 14 1 5 /2/18 13 9 5/9/18 13 3 5/10/18 14 10 5/14/18 14 1 5/16/18 14 7 5/18/18 13 3 5/24/18 13 3 5/28/18 14 1 5/29/18 14 1 5/30/18 14 5 6/6/18 13 3 6/7/18 13 3 6/8/18 13 2 6/13 /18 13 8 6/14/18 13 2 6/18/18 13 1 6/19/18 13 2 6/20/18 13 3 6/21/18 13 2 6/26/18 13 2 6/27/18 13 9 6/28/18 13 2 6/29/18 13 4 7/5/18 13 3 7/18/18 13 10 4. The laboratory processed and reported one hundred forty two (142) frozen sections patient's samples those days. 5. The testing personnel confirmed on October 24, 2019 that the laboratory documented temperatures out of the established temperature range in tissue processor area and did not take any remedial or corrective actions.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on procedure manual, histopathology quality control records review (years 2018-2019) and pathology laboratory histotechnologist interview at 10:45 AM on October 24, 2019, it was determined that the laboratory director failed to fulfil his responsibilities and duties to ensure compliance with the laboratory test procedures. Refer to D6084 and D6093.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on procedure manual, histopathology quality control records review (years 2018-2019) and interview with the pathology laboratory histotechnologist at 10:45

	AM on October 24, 2019, it was determined that the laboratory director failed to ensure the optimal environmental conditions of the frozen section processing area. Refer to D3011.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on procedure manual, histopathology quality control records review (years 2018-2019) and interview with the pathology laboratory histotechnologist at 11:00 AM on October 24, 2019, it was found that the laboratory director did not assure that the quality control procedures related to instrument temperature of the Leica Cryostat HESLP, room temperature for tissue process area not airflow records for Fume Absorber. The finding includes: 1. The testing personnel did not take any remedial actions when temperature ranges for the Leica Cryostat HESLP (CM1850-3-1), tissue processor area not fume absorber readings were outside the expected ranges. side the established range. Refer to D5781.