

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658172	(X3) Date Survey Completed 03/07/2018
Name of Provider or Supplier Southern Pathology Services Inc	Street Address, City, State 234 Calle A Parque Industrial Sabanetas, 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
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by:</p> <p>1. Based on physical plant observation and interview with the laboratory general cytology supervisor on March 7, 2018 at 8:45 AM , it was determined that the laboratory did not have a ventilation system to ensure properly removes of vapors or fumes in the area where the cytology smears were stained by Leica auto strainer are located. The findings include: a. On March 7, 2018 at 8:45 AM, its observed that the laboratory did not have a ventilation system (fumes extractor) to ensure properly removes of vapors or fumes in the area where the cytology smears were stained by Leica auto strainer and the two Thin-prep systems are located. b. The general cytology supervisor confirmed on March 7, 2018 at 8:55 AM, that the laboratory did not have a fumes extractor in this area. She stated that the laboratory cytology working area was relocated in this new area about threes weeks ago. 2. Based on procedures manual, vapors check records review and laboratory staff interview on March 7, 2018 at 11:50 AM, it was determined that the laboratory failed to follow written procedures to perform every six moths the vapors check of the histology pre-analytic laboratory personnel from January 2017 to March 7, 2018. The findings include: a. The procedures manual establishes to perform the laboratory personnel vapors check every six months. b. The vapors check records showed that the laboratory did not perform every six moths the vapor check of the histology pre-analytic system laboratory personnel from January 2017 to March 7, 2018. The laboratory performed the vapor check in two out of three histology pre-analytic system laboratory personnel on May 23, 2017 during the period from January 2017 to March 7, 2018. c. The laboratory staff confirmed on March 7, 2018 at 12:10 PM, that the laboratory did not perform every six months the vapor check in two out of three histology pre-analytic system</p>

laboratory personnel from January 2017 to March 7, 2018. 3. Based on BS manufacturer's instructions, calibration records review and laboratory staff interview on March 7, 2018 at 9:30 AM, it was determined that the laboratory failed to follow manufacturer's instructions for the annual calibration of the Class II safety safety cabinet since February 2017. This safety cabinet was located in the cytology working area. The findings include: a. The BS Class II safety safety cabinet manufacturer's instructions require an annual calibration for this safety cabinet. b. The BS Class II safety safety cabinet showed that the calibration was due since February 2017. c. The laboratory staff confirmed on March 7, 2018 at 9:30 AM, that the annual calibration of the BS Class II safety safety cabinet was due since February 2017.

D5305

TEST REQUEST
CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:
Based on Pap smears requisition records (December 2017) review and cytology supervisor interview on March 7, 2018 at 10:10 AM, it was determined that the laboratory failed to ensure that 5 out of 5 Pap smears requisitions have the required information. The findings include: 1. The Pap smears requisition records (December 2017) showed that the laboratory did not ensure that the following 5 out of 5 Pap smears requisitions (December 20, 2017) include the required information: a. The 4 out of 5 Pap smears requisitions did not include the last menstrual period information: #23763, #23764, #23766 and #23767. b. The 3 out of 5 Pap smears requisitions did not include clinical historic information: #23763, #23764 and #23765. c. The 2 out of 5 Pap smears requisitions did not include the date of collection: #23763 and #23764. 2. The cytology supervisor confirmed on March 7, 2018 at 10:10 AM, that those Pap smears requisition did not have the required information.

D6083

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:
Based on physical plant observation, environmental test log review and interview with the cytology supervisor and laboratory staff on March 7, 2018 at 9:30 AM, it was

determined that the laboratory director did ensure that the environmental conditions (environmental vapors and fumes) were appropriate for specimen testing and handling. Refer to D3001.