

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2080975	(X3) Date Survey Completed 02/07/2024
Name of Provider or Supplier Florida Physician Specialists Llc	Street Address, City, State 710 Lomax St, Jacksonville, 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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, observation and interview the laboratory failed to follow written policies and procedures to ensure positive patient identification during nongynecologic specimen processing. Findings include: 1. The laboratory failed to follow the procedure PROCEDURE FOR ACCESSIONING & LABELING SPECIMENS which stated: "-Specimens are entered into the LIS System and assigned a unique Accession Number (e.g.C99-1234 for cytology specimens). - Label the container in which the specimen is received with the accession number on the side of the container. -Throughout the specimen accessioning, processing, labelling procedures of testing, staff are to ensure that specimen name and numbers match and correspond." 2. The laboratory failed to follow the procedure CENTRIFUGE PROCEDURE which stated: "Label a 50 ml conical centrifuge tube with the cytology case number, the patient's last name." 3. During an observation of nongynecologic specimen processing on February 6, 2024 at 12:10 PM the Cytology Processor failed to label the specimen centrifuge tubes with a patient identifier. a. The Cytology Processor wrote a partial accession number on the specimen centrifuge tube cap. The Cytology Processor failed to write the "C24" portion of the accession number on the specimen centrifuge tube cap. b. The Cytology Processor failed to label the specimen centrifuge tubes with the cytology case number and the patient's last name. When the centrifuge tube cap was removed, the specimen centrifuge tube was unlabeled and did not have a patient identifier. c. The laboratory failed to ensure 10 of 10 patient specimens were labeled with a positive patient identifier during</p>

nongynecologic specimen processing on February 6, 2024. Specimens include: -C24-125 -C24-126 -C24-127 -C24-128 -C24-129 -C24-130 -C24-131 -C24-132 -C24-133 -C24-134 4. During an interview on February 6, 2024 at 12:27 PM these findings were confirmed with the Laboratory Manager and the Cytology Processor.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of competency assessment records and interviews with the Laboratory Manager the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of two of two Technical Supervisors in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the Technical Supervisors who performed cytology testing on patient specimens. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for the cytology duties performed by two of two Technical Supervisors in 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During interviews on February 5, 2024 at 11:40 AM and February 6, 2024 at 8: 10 AM these findings were confirmed with the Laboratory Manager.

D5309

TEST REQUEST
CFR(s): 493.1241(e)

If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

This STANDARD is not met as evidenced by:
Based on review of final cytology test reports and corresponding laboratory requisitions and interview with the Laboratory Manager the laboratory failed to ensure that cytology specimen information was transcribed accurately into the laboratory information system (LIS) for six of twenty cytology specimens sampled from December 2023. Findings include: 1. The Survey Team compared 20 final cytology test reports from December 2023 with corresponding laboratory requisitions. Six of 20 final cytology test reports failed to have accurate specimen information transcribed into the LIS. Specimen information includes: -Case #: C24-1345 Lab Requisition: ICD codes 1233.9; C67.4; R31.0; R39.89 Cytology Test Report: ICD codes 1233.9 and C67.4 not entered -Case #: C24-1367 Lab Requisition: collection date 12/20/21 Cytology Test Report: collection date 12/19/2023 -Case #: C24-1372 Lab Requisition: ICD code N39.0 Cytology Test Report: ICD code not entered -Case #: C24-1377 Lab Requisition: voided urine Cytology Test Report: bladder wash -Case #: C24-1390 Lab Requisition: bladder wash catheter urine Cytology Test Report: catheter urine -Case #: C24-1393 Lab Requisition: clinical hematuria Cytology Test Report: hematuria not

	<p>entered 2. During an interview on February 6, 2024 at 12:30 PM these findings were confirmed with the Laboratory Manager.</p>
<p>D5391</p>	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews with the Laboratory Manager the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic cytology systems. The laboratory failed to document preanalytic quality assessment activities for cytology during 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the preanalytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of preanalytic quality assessment activities during 2023 and January 1, 2024 to the date of the survey in 2024. a. The laboratory failed to document a system for monitoring and evaluating the accuracy of transcription of patient specimen information into the final test report. (See D5309) 3. During an interview on February 6, 2024 at 9:50 AM these findings were confirmed with the Laboratory Manager.</p>
<p>D5473</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of quality control records and interview with the Laboratory Manager the laboratory failed to test staining materials for intended reactivity of the Papanicolaou stain used for nongynecologic cytology specimen slides for each day of use in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide laboratory records documenting that the characteristics of the Papanicolaou stain used for nongynecologic cytology slide preparations were assessed each day of use in 2023 and January 1, 2024 to the date of the survey in 2024. 2. During an interview on February 5, 2024 at 1:50 PM these findings were confirmed with the Laboratory Manager.</p>
<p>D5637</p>	<p>CYTOLOGY CFR(s): 493.1274(d)(1)(ii)</p>

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of workload limit reassessment records and interview with the Laboratory Manager the laboratory failed to establish and follow written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of cytology specimens. The Technical Supervisor failed to reassess a maximum workload limit for two of two Technical Supervisors in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would reassess a maximum workload limit for the Technical Supervisors at least every six months and adjust when necessary. The laboratory failed to provide written policies and procedures to detail what performance criteria would be reviewed as part of a workload reassessment. 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a maximum workload limit for two of two Technical Supervisors in 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on February 6, 2024 at these findings were confirmed with the Laboratory Manager.

D5659

CYTOLOGY

CFR(s): 493.1274(e)(6)

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview with the Laboratory Manager the laboratory failed to establish written policies and procedures to ensure corrected test reports indicated the basis for correction on the corrected test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected test reports indicated the basis for correction on the corrected test report. 2. During an interview on February 6, 2024 at 10:00 AM these findings were confirmed with the Laboratory Manager.

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 review of laboratory policies and procedures, lack of quality control records and interview with the Laboratory Manager the Laboratory Director failed to ensure

written quality control policies and procedures for cytology were followed. Findings include: 1. The Laboratory Director failed to ensure the written policy and procedure titled CYTOLOGY STAINING-QUALITY CONTROL was followed. The policy stated: "A Pathologist or designee, will check the Cytology staining quality on a daily basis." Refer to D5473 2. During an interview on February 5, 2024 at 1:50 PM these findings were confirmed with the Laboratory Manager.