

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  38D2032720	<b>(X3) Date Survey Completed</b>  05/08/2024
<b>Name of Provider or Supplier</b>  Providence Laboratory Services	<b>Street Address, City, State</b>  4400 Ne Halsey St Bldg 3, Ste 300, Portland, OR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, competency assessment records and interview with Staff C the laboratory failed to follow written policies and procedures to assess the competency of Cytotechnologists. The laboratory failed to assess the competency of one of two Cytotechnologists in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory policy and procedure CAREGIVERS COMPETENCY POLICY stated: "-Performing Competency Assessment -Cytology Staff -When evaluating competency of Cytology dept staff, include the 'Proficiency of Cytotechs' form in the competency packet." "-Schedule for Competency Evaluations -Moderate and high complexity testing: - Unless the caregiver has been with the organization less than one full year, initial competency assessment then annually (every 12 months) thereafter. -If annual competency assessment is not performed within the 13 month time requirements, the employee must be removed from that job assignment until competency can be assessed." 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for one of two Cytotechnologists in 2023 and January 1, 2024 to the date of the survey in 2024. Cytotechnologist includes: Cytotechnologist A 3. During an interview on May 7, 2024 at 9:15 AM, Staff C /Senior Manager of Anatomic Pathology (AP) provided a competency assessment for Cytotechnologist B dated 02/2023 and stated "we do not have a competency assessment for Cytotechnologist A" for 2023 and January 1, 2024 to the date of the survey in 2024. 4. During an interview on May 7, 2024 at 2:30 PM, Staff C/Senior Manager of AP confirmed that competency assessments were not performed for one</p>

of two Cytotechnologists for 2023 and January 1, 2024 to the date of the survey in 2024.

**D5637**

CYTOLOGY  
CFR(s): 493.1274(d)(1)(ii)

(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 records and interview with Staff C the laboratory failed to follow written policies and procedures to reassess a maximum workload limit at least every six months for two of two Cytotechnologists in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory policy and procedure CYTOTECHNOLOGISTS AND PATHOLOGISTS WORKLOAD LIMITS PROCEDURE stated: "The cytopathology medical director (technical supervisor) must establish the maximum workload limit (based on capability/recorded performance evaluation) for each individual who screens slides. The workload limit is reassessed at every six months. Performance is evaluated using the following: (1) re-evaluation of 10-percent of the cases interpreted to be negative by cytotechnologists; (2) comparing the cytotechnologist's interpretation in gynecologic specimens with the final cytologic diagnosis; and (3) comparing the cytotechnologist's interpretation in non-gynecologic specimens with the final cytologic and/or surgical diagnoses. TBS diagnostic rates and SIL ratios are reviewed and measured against CAP benchmark percentiles. This analytics helps to ensure sensitive and specific diagnostic interpretations. Retrospective reviews, comparison of individual statistics with overall lab statistics, pathologists' feedback, cyto/histo correlation data, and competency assessments are also contributory quality monitors and affect determinations." 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months in 2023 and January 1, 2024 to the date of the survey in 2024 for two of two Cytotechnologists. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 3. During an interview on May 7, 2024 at 2:30 PM, Staff C/Senior Manager of AP confirmed that workload limit reassessments were not performed for two of two Cytotechnologists for 2023 and January 1, 2024 to the date of the survey in 2024.

**D5647**

CYTOLOGY  
CFR(s): 493.1274(d)(4)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures, lack of workload limit records and interview with Staff C the laboratory failed to follow written policies and procedures to ensure records were available to document the workload limit for two of two Cytotechnologists who performed screening of cytology specimens in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The laboratory

failed to follow written policies and procedures to document the workload limit for the Cytotechnologists. Refer to D5637 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for two of two Cytotechnologists in 2023 and January 1, 2024 to the date of the survey in 2024. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 3. During an interview on May 7, 2024 at 2:30 PM, Staff C/Senior Manager of AP confirmed that workload limit reassessments records could not be provided for two of two Cytotechnologists for 2023 and January 1, 2024 to the date of the survey in 2024.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures, competency assessment records and interviews the Laboratory Director failed to ensure written policies and procedures were followed to assess, monitor and maintain the competency of Laboratory Assistants in 2023 and January 1, 2024 to the date of the survey in 2024. The Laboratory Director failed to ensure written policies and procedures were followed to assess, monitor and maintain the competency of Cytotechnologists in 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Laboratory Director failed to ensure written policies and procedures were followed to assess the competency of Laboratory Assistants performing cytology duties for 2023 and January 1, 2024 to the date of the survey in 2024. a. The laboratory policy and procedure CAREGIVERS COMPETENCY POLICY stated: "-Schedule for Competency Evaluations -Non-technical competency: -Initial competency assessment then annually (every 12 months) thereafter. -If annual competency assessment is not performed within the 13 month time requirements, the employee must be removed from that job assignment until competency can be assessed." b. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for three of three Laboratory Assistants in 2023 and January 1, 2024 to the date of the survey in 2024. Laboratory Assistants include: -Laboratory Assistant A -Laboratory Assistant B -Laboratory Assistant C c. During an interview on May 7, 2024 at 10:00 AM, Staff C/Senior Manager of AP stated "we do not have a competency assessment for the laboratory assistants" for 2023 and to the date of the survey in 2024. 2. The Laboratory Director failed to ensure written policies and procedures were followed to assess the competency of one of two Cytotechnologists for 2023 and January 1, 2024 to the date of the survey in 2024. Refer to D5209 3. During an interview on May 7, 2024 at 2:30 PM, Staff C/Senior Manager of AP confirmed that competency assessments were not performed for one of two Cytotechnologists and three of three Laboratory Assistants for 2023 and to the date of the survey in 2024.

**D9999**

By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under

the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.