

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  38D2061880	<b>(X3) Date Survey Completed</b>  09/19/2022
<b>Name of Provider or Supplier</b>  Nepenthe Laboratory Services	<b>Street Address, City, State</b>  1710 Willow Creek Cir, Suite 2, Eugene, 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>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 interview with the General Supervisor (GS) and Technical Supervisor (TS) #2 and review of four (4) Testing Personnel (TP) competency assessments and training records during survey on 09/19/2022, the laboratory failed to ensure that all TP received the required competency assessment and training before reporting patient test results. Finding include: 1. Review of competency assessments, the laboratory failed to ensure competency assessment for four (4) of four (4) testing personnel performing patient urine drug screens on the Mindray BS-48- and Liquid Chromatography/Mass Spectrometry (LC/MS) analysis used to test/confirm patient urine specimens for drugs of abuse and other pharmaceutical drugs: Testing Personnel Analyzer Dates TS#2/TP -1 LC/MS 04/25/2022 GS/TP-2 LC/MS 06/22/2022 TP-3 LC /MS 04/29/2022 TP-3 Mindray BS-480 05/02/2022 TP-4 Mindray BS-480 No record of competency for 2020, 2021, 2022 2. Review of competency records for TP #4 revealed that the laboratory failed to perform competency training or competency assessment for TP#4 who performs moderately complex testing on the Mindray BS-480 chemistry instrument for 2020, 2021, 2022. 3. Review of the competency assessment for TP#3 revealed the laboratory failed to include all six (6) elements of competency assessment on the moderately complex Chemistry instrument Mindray BS-480 chemistry instrument and the LC/MS analyzer used to test patient urine specimens for drugs of abuse and urine adulterants. 4. The GS / TP-2 and the TS#2 /TP-1 confirmed by interview on 09/19/2022 at approximately 12:00 pm the lack of performing competency assessment for all testing personnel which include the six (6) elements. 5. The test records indicate the lab performed 1,219,538 tests annually.</p>

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1239(a)

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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of the Quality Assessment (QA) Review policy (Nepenthe Q-06) and random audit of the monthly QA Audit checklist dated August 2022 and interview with the Technical Supervisor (TS)#2 and General Supervisor (GS) during survey 09/19/2022, the laboratory failed to follow their QA policy. Findings include: 1. In the Nepenthe policy for QA, the "Purpose" in the Q-06 document states "The purpose of the Quality Assessment Review Policy is to assure that all pertinent aspects of the laboratory department are monitored and reviewed to assure that patient testing is completed in a safe and compliant manner to meet regulatory requirements". 2. Upon review of the Monthly Laboratory Audit for August 2022, the four (4) page document is a checklist. On page one (1), under Personnel Policies, the first check box states that "Have all Lab Personnel been trained, and the training documented? The person completing this audit form answered "YES". See D5209 3. Upon review of the Monthly Laboratory Audit for August 2022, the four (4) page document is a checklist. On page one (1), under Personnel File Checklists, the first check box states "Are all testing personnel evaluated at six months after beginning patient testing and then at least annually thereafter". The person completing this audit form answered "YES". See D5209 4. Upon review of the August 2022 QA Audit form signed 09/02/2022, it was revealed that the TP performing the audit is TP#4, who has no competency records for 2020, 2021 and 2022. 5. The Laboratory Director's signature and date is absent.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of personnel training and competency assessment records and interview with the General Supervisor (GS) and Technical Supervisor #2 (TS), the Laboratory Director (LD) failed to ensure that testing personnel (TP) performing both moderate and high complexity testing have the requisite competency assessment and training. Findings include: 1. Upon review of TP competency records, the LD failed to ensure adequate competency assessment is being adequately performed for all testing personnel. The GS and TS#2 confirmed this deficient practice during interview on 09/19/2022 at approximately 12:00 pm. 2. See D5209.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of this laboratory's policies and procedures and interview with the General Supervisor (GS) and Technical Supervisor #2 (TS), the Laboratory Director (LD) failed to specify in writing which testing personnel (TP) were approved to perform patient testing procedures and training of TP. Findings include: 1. During survey 09/19/2022, the lack of written documentation for the GS and TS #1 and #2 regarding the responsibilities and duties for training and evaluation of TP was revealed. 2. During survey 09/19/2022, the lack of written documentation of TP approved for patient testing or TP approved for competency assessment and training revealed that there was no written documentation identifying which examinations and procedures each individual is authorized to perform. 3. This was confirmed by interview on 09/19/2022 by the TS#2 and GS at approximately 1230 pm. 4. The laboratory records indicate the laboratory performs 1,219,538 tests annually.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) training and competency assessment records and interview with Technical Supervisor (TS) #2 and the General Supervisor (GS) during survey 09/19/2022, TS #1 and #2 failed to ensure all TP had adequate competency assessments performed before performing patient testing. Findings include: 1. Review of TP competency assessment records revealed that both TS's failed to ensure that all TP had current and ongoing competency assessments which included the six (6) elements of assessment. See D5209