

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1101815	(X3) Date Survey Completed 04/30/2024
Name of Provider or Supplier Virtuous Pain Center DbA	Street Address, City, State 3401 S White Mountain Rd, Show Low, AZ	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of manufacturer's package inserts presented for review for testing performed on the Indiko 500 Plus analyzer and interview with the facility personnel, the laboratory failed to retain the manufacturer's package inserts for at least 2 years for each lot of Quality Control (QC) and test reagent material used on the analyzer. Findings include: 1. The laboratory performs urine drug screen (UDS) testing on patients under the subspecialty of Toxicology with an annual reported test volume of 18,000. Patient testing began in October 2021. 2. During the survey conducted on 4/30/2024, no evidence was presented for review to indicate the laboratory retained the manufacturer's assay information sheets for at least 2 years for each lot of QC and test reagent material used on the Indiko 500 Plus analyzer. 3. The facility personnel interviewed on 4/30/2024 at 2:20 PM confirmed the laboratory failed to retain the manufacturer's assay information sheets for at least 2 years for each lot of QC and test reagent material used on the analyzer indicated above.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and</p>

rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual and interview with the facility personnel, the laboratory failed to follow established policies and procedures related to specimen labeling. Findings include: 1. The laboratory performs urine drug screen (UDS) testing on patients under the subspecialty of Toxicology with an annual reported test volume of 18,000. Patient testing began in October 2021. 2. The laboratory's established policy titled 'Urine Drug Testing Specimen Labeling, Handling and Retention' states: "Label all specimens in the presence of the patient as follows: - Patient's name - Second unique identifier (MR#, DOB, etc.) -Initials of clinical staff overseeing the collection." 3. One out of one patient specimens reviewed during the survey showed that the laboratory failed to label specimens with two complete patient identifiers (L. Rios collected on 4/24/24). 4. The facility personnel interviewed on 4/30/2024 at 2:40 PM confirmed that the laboratory personnel were not following established policies and procedures related to specimen labeling.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control (QC) records, lack of QC lot correlation documentation and interview with the facility personnel, the laboratory failed to verify the criteria for acceptability of quality control materials. Findings include: 1. The laboratory performs semi-quantitative urine drug screen (UDS) testing on patients under the subspecialty of Toxicology with an annual reported test volume of 18,000. Patient testing began in October 2021. 2. No documentation was presented for review to indicate the laboratory verified the criteria for acceptability of each lot of control material used on the analyzer indicated above from October 2021 through the date of the survey on 4/30/2024. 3. The facility personnel interviewed on 4/30/2024 at 2:10 PM confirmed the laboratory failed to document the criteria for acceptability of control lots used on the Indiko 500 Plus analyzer. 4. The number of QC lots used on the analyzer from October 2021 through the date of the survey could not be determined at the time of the survey.