

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D1076222	<b>(X3) Date Survey Completed</b>  12/18/2025
<b>Name of Provider or Supplier</b>  Beresh Pain Management Inc	<b>Street Address, City, State</b>  840 Northwest Washington Boulevard Suite C, Hamilton, OH	
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>D5313</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>(b) The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with General Supervisor (GS) #1, the laboratory failed to document the time in which urine specimens were collected. This deficient practice had the potential to affect 1,684 out of 1,684 patients tested in the subspecialty of Toxicology from 08/20/2024 through 12/18/2025. Findings were as follows: 1. Review of three laboratory's patient test reports found the "Time Collected" recorded as "12:00:00 AM". 2. Review of the laboratory's policies and procedures titled, "QMS &amp; Safety Policies", approved by the Laboratory Director on 4/18/24, found no mention of specimen collection time documentation. 3. An interview on 12/18/2025 at 2:15 PM with the GS #1, verified the policy did not address specimen collection times and confirmed the urine specimen collection times on the patient reports were a default time, and the actual urine specimen collection times were not documented.</p>
<b>D5439</b>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A</p>

complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to perform and document calibration verification procedures for urine toxicology confirmations at least every 6 months. This deficient practice had the potential to affect 1,684 out of 1,864 patients tested in the subspecialty of Toxicology from the laboratory's initial inspection on 08/20/2024 through 12/18/2025. Findings Include: 1. Review of a document titled "Memorandum for Record", signed and dated by the LD on 12/17/2025, found the following statement: "A calibration verification procedure determining the Analytical Measurement range (AMR) was performed prior to testing patient specimens in May of 2024. They were not performed in when next due in November of 2024 due to turnover in personnel. They were next performed in July of 2025, but the outcome was unsuccessful by a former employee. In December of 2025 the calibration verification or AMR study was performed successfully." 2. Review of the laboratory's analytical measurement range, (AMR), data for urine toxicology confirmations found the following: Date AMR performed: 12/2025 There was no other AMR test documented as being performed from 08/20/2024 through 12/18/2025. 3. An interview on 12/18/2025 at 3:00 PM with the LD confirmed the lab failed to perform calibration verification for urine toxicology confirmations at least every 6 months.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1299(a)

(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to follow written policies and procedures, and document all assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. This deficient practice had the potential to affect 1684 out of 1684 patients tested in the subspecialty of Toxicology from 08/20/2024 through 12/18/2025. Findings Include: 1. Review of the laboratory's policy and procedure titled "QMS: LABORATORY QUALITY MANAGEMENT PROGRAM Version 1.0 Effective 4/25/2024", found the following statement: "...iv. Inspections, root cause analysis audits and preventative and corrective actions as well as process improvement are performed to ensure the laboratory is delivering quality results to meet or exceed the clients' expectations. 2. Review of laboratory documentation revealed no evidence of the laboratory completing inspections, root cause analysis audits, preventative measures, corrective actions, and process

improvements. 3. An interview on 12/18/2025 at 3:00 PM with the LD verified the laboratory did not follow the policy and procedure for the Quality Management Program.