

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1092620	(X3) Date Survey Completed 02/03/2025
Name of Provider or Supplier Physical Medicine Rehabilitation And Consultant	Street Address, City, State 21675 Coolidge Hwy Suite A, Oak Park, MI	
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to perform and document corrective actions for its qualitative urine toxicology testing using the Easy RA analyzer when it had flagged absorbance issues for one of 32 patient test reports generated on 2/1/25. Findings include: 1. A review of patient test reports for patients tested on 2/1/25 revealed one patient test report had the following results: a. Two negative results for Amphetamine. One result had the instrument flag "RN". b. Two results for Barbiturates: i. The first result was an "-E-" and the instrument flag "HN". ii. The second result was positive with the instrument flag "RN". c. Two results for benzodiazepines: i. First result was negative with the instrument flag "RN". ii Second result was positive with the instrument flag "HA". d. Two negative results for cocaine and the instrument flags "HA" for both results. e. Two results for opiates: a. The first result was negative with the instrument flag "HA". b. The second result was positive with the instrument flag "RN". f. Two positive results for oxycodone with the instrument flags "HA". 2. A review of the laboratory's "Medica Easy RA Operator's Manual" revealed a section titled "Flag" stating, "Result Flag codes display if the results are out of range or if there is a measurement error for</p>

Sample tests. The Flag field may be blank, it may contain up to 2 two-letter codes, or it may contain an error message (-E-). The number of flagged results is located next to the flag icon." 3. A review of the laboratory's "Medica Easy RA Operator's Manual" revealed a table titled "Measurement Error Flag Descriptions" revealed what each of the codes found on the patient test report are: a. "HN" is short for "High Reactions Rate Noise (System)" and states, "Two or more points are 0.003 Abs. away from the line of best fit. Results are not shown." b. "RN" is short for "Reaction Rate Noise (System)" and states, "One point is more than 0.003 Abs. units away from the line of best fit. Point is eliminated from calculations. Results are shown." c. "HA" is short for "High Absorbance (System)" and states, "Absorbance greater than 2.5 Abs. units. Results are shown." 4. An interview on 2/3/25 at 12:37 pm with the technical consultant confirmed the patient's test report had conflicting results, instrumentation flags, and confirmed the urine specimen had already been discarded. The surveyor requested corrective action for this patient and it was not made available.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
. Based on observation, record review, and interview with the technical consultant, the laboratory director failed to ensure frozen urine toxicology specimens were protected from freezer temperature fluctuations. Refer to D5413.