

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2033659	<b>(X3) Date Survey Completed</b>  01/21/2020
<b>Name of Provider or Supplier</b>  Uhealth Pathology At Rmsb	<b>Street Address, City, State</b>  1600 Nw 10th Ave Ste 7085a, Miami, FL	
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>D0000</b>	A recertification survey conducted on 01/21/2020 found that Uhealth Pathology at RMSB clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing policy, proficiency testing (PT) records and laboratory director (LD) interview, the laboratory failed to perform the required twice a year accuracy verification of testing for the quantification of Ketamine, Norketamine, Ritalinic Acid, Tapentadol and Zolpidem tested in urine toxicology for 2 out of 2 years reviewed (2018-2019). Findings include: -Review of Laboratory Procedure Proficiency Testing policy # 3.0.11 revision 3, revealed that on a Note on page 1 the policy stated that " For those tests for which CAP does not require enrollment in PT for clinical test panels, the laboratory must participate at least annually in either external PT or exercise an alternative performance assessment system for determining the reliability of analytic testing." The policy failed to state that the analytes must be verified at least twice a year. -Review of CAP PT menu revealed that no quantification was performed of the analytes: Ketamine, Norketamine, Ritalinic Acid, Tapentadol and Zolpidem. -Review of split samples study revealed that the laboratory performed one split sample evaluation for the quantification of Ketamine, Norketamine, Ritalinic Acid, Tapentadol and Zolpidem in November 2018 and one in November 2019. During an interview on 01/21/2020 at 12: 30 PM, the LD confirmed that the laboratory failed to verify the accuracy for the quantification of the analytes of reference at least twice a year for the years of above reference.</p>