

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2115989	<b>(X3) Date Survey Completed</b>  12/19/2023
<b>Name of Provider or Supplier</b>  Regional Cancer Care Assoc At Toms River	<b>Street Address, City, State</b>  40 Beylea Road, Toms River, NJ	
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>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> 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 surveyor review of Patient Test Records (TR), Procedure Manual (PM), the Medonic M Series User Manual and interview with the Technical Consultant (TC), the laboratory failed to perform corrective action when patient TR had flagged codes for Hematology tests from 11/1/21 to the date of survey. The findings include: 1. The PM states " Note: Physicians may bring CBC's that warrant review to local hospital lab or reference lab for smear review. They will perform differential review of smear." 2. Patient Identification number (PIN) 520718 had "BD" flagged analyte results for LYM%, MID%, GRA%, LYM, MID and GRAN. 3. PIN 516383 had "TM" flagged analyte results for LYM%, MID%, GRA%, LYM, MID and GRAN. 4. The Medonic M Series User Manual for the "BD" and "TM" flags states "Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." 5. There was no documented evidence corrective action was taken for the aforementioned flagged results. 6. The TC confirmed on 12/19/23 at 11:15 am that corrective action was not performed.</p>