

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0391462	(X3) Date Survey Completed 10/27/2021
Name of Provider or Supplier Tosa Pediatrics	Street Address, City, State 8651 W North Ave, Wauwatosa, WI	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of laboratory specimens and interview with the technical consultant, the laboratory does not have an established method to ensure positive identification of patient specimens from the time of collection through completion of testing. Findings include: 1. Observation of two patient specimens, patient 1 and patient 2, on October 27, 2021 at 10:25 AM, being tested on the BioFire Diagnostics FilmArray Torch analyzer revealed patient specimens in individual plastic bags with the patient name on a piece of paper in the bag. Further observation revealed no patient identification present on the specimens. 2. Interview with the technical consultant on October 27, 2021 at 10:28 AM confirmed the laboratory does not have an established method to ensure positive identification of patient specimens from the time of collection through completion of testing.</p>