Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 23D0879676	**(X3) Date Survey Completed** 10/07/2024
Name of Provider or Supplier Trinity Health Rheumatology East Paris	**Street Address, City, State** 1155 E Paris Ave Se Suite 100, Grand Rapids, 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**
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to follow established general laboratory systems quality assessment policies and procedures for 2 (2023, 2024) of 2 years reviewed. Findings include: 1. A record review of the laboratory's quality assessment documentation revealed a quality assessment had been performed on 10/11/2022. Quality assessment documentation was not present for 2023 or 2024. 2. A review of the "Laboratory Procedure Manual: Synovial Flid Crystal Examination, CLIA Regulation Compliance Documentation," states on page 4, section VI, "Quality Assurance", number III: "Yearly a quality assurance audit of 9 patient charts will be performed utilizing the 'Quality Assurance Act' worksheet to ensure that laboratory findings are being accurately: recorded in the laboratory log, source of sample documented, recorded in patient EMR." 3. An interview conducted on 10/07/2024 at 1:55pm with the laboratory Office Manager confirmed that records were not present.