

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D1002099	<b>(X3) Date Survey Completed</b>  02/26/2020
<b>Name of Provider or Supplier</b>  Susan G Woods Md	<b>Street Address, City, State</b>  20 Ohltown Road, Youngstown, OH	
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>D5803</b>	<p>TEST REPORT CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Business Manager (BM), the laboratory failed to maintain legible and understandable tissue biopsy interpretation results as part of the patient's paper chart in four out of four corresponding patient test records and final test reports. All patient tissue biopsy interpretation results had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's test report template for tissue biopsy reporting, provided on the date of the inspection, revealed patient demographic information, the patient's clinical history, the tissue biopsy gross description and a box of 19 pre-typed diagnoses with an additional space labeled "Other:___". To the right of this box of the pre-typed diagnoses were six blank lines for hand written notes and interpretations that did not meet the diagnostic criteria of the 19 pre-typed diagnoses. 2. Review of two out of two of the laboratory's 2018 and two out of two of the laboratory's 2019 corresponding patient tissue biopsy test records and final test reports found illegible, hand written biopsy interpretations in the patient's paper chart from the dates of procedure and for eight out of eight of the specimen sources as listed below: Patient A 04/16/2018; right neck medial right neck lateral right cheek Patient B 05/31/2018; right upper back Patient C 01/02/2019; left back posterior left neck posterior right neck Patient D 01/10/2019; right scalp 3. The Inspector was unable to read or extrapolate the written tissue biopsy diagnostic interpretations for all four of the final test reports reviewed containing eight out of eight individual specimen sources as listed above and requested the BM to provide the tissue biopsy interpretations. The</p>

BM confirmed that the hand written tissue biopsy interpretations were illegible and therefore not readily available on the date of the inspection. The interview occurred on 02/26/2020 at 2:55 PM.