General Comments & Additional Information
Clinical Info: NORMAL REPORT

Ordered Items
HCV FibroSure

<table>
<thead>
<tr>
<th>TESTS</th>
<th>RESULT</th>
<th>FLAG</th>
<th>UNITS</th>
<th>REFERENCE INTERVAL</th>
<th>LAB</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV FibroSURE Results:</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Fibrosis Score</td>
<td>0.55</td>
<td>High</td>
<td></td>
<td>0.00 - 0.21</td>
<td>01</td>
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<tr>
<td>Fibrosis Stage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>01</td>
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<tr>
<td></td>
<td>F2 - Bridging fibrosis with few septa</td>
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<tr>
<td>Necroinflamm Activity Score</td>
<td>0.24</td>
<td>High</td>
<td></td>
<td>0.00 - 0.17</td>
<td>01</td>
</tr>
<tr>
<td>Necroinflamm Activity Grade</td>
<td>A0-A1</td>
<td></td>
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<td>01</td>
</tr>
</tbody>
</table>

Analysis:
Alpha 2-Macroglobulins, Qn  250  mg/dL  110 - 276  01
Haptoglobin             100  mg/dL  33 - 346  01
Apolipoprotein A-1         125  mg/dL  116 - 209  01
Bilirubin, Total          0.9   mg/dL  0.0 - 1.2  01
GGT                     45    IU/L  0 - 60   01
ALT (SGPT) P5P            35    IU/L  0 - 40   01

Interpretations:  
Quantitative results of 6 biochemical tests are analyzed using a computational algorithm to provide a quantitative surrogate marker (0.0-1.0) for liver fibrosis (METAVIR F0-F4) and for necroinflammatory activity (METAVIR A0-A3).

Fibrosis Scoring:
<0.21 = Stage F0 - No fibrosis
0.21 - 0.27 = Stage F0 - F1
0.27 - 0.31 = Stage F1 - Portal fibrosis
0.31 - 0.48 = Stage F1 - F2
0.48 - 0.58 = Stage F2 - Bridging fibrosis with few septa
0.58 - 0.72 = Stage F3 - Bridging fibrosis with many septa
0.72 - 0.74 = Stage F3 - F4
>0.74 = Stage F4 - Cirrhosis

Necroinflamm Activity Scoring:
<0.17 = Grade A0 - No Activity
<table>
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<tr>
<td>0.17 - 0.29</td>
<td>Grade A0 - A1</td>
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<tr>
<td>0.29 - 0.36</td>
<td>Grade A1 - Minimal activity</td>
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<td>0.36 - 0.52</td>
<td>Grade A1 - A2</td>
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<td>0.52 - 0.60</td>
<td>Grade A2 - Moderate activity</td>
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<td>0.60 - 0.62</td>
<td>Grade A2 - A3</td>
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<td>&gt;0.62</td>
<td>Grade A3 - Severe activity</td>
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Limitations:

The negative predictive value of a Fibrotest score <0.31 (absence of clinically significant fibrosis) was 85% when compared to liver biopsy in 1,270 HCV infected patients with a 38% prevalence of significant liver fibrosis (F2, 3 or 4). The positive predictive value of a Fibrotest score >0.48 (F2, 3, 4) was 61% in that same patient cohort. HCV FibroSURE is not recommended in patients with Gilbert Disease, acute hemolysis (e.g. HCV ribavirin therapy mediated hemolysis) acute hepatitis of the liver, extra-hepatic cholestasis, transplant patients, and/or renal insufficiency patients. Any of these clinical situations may lead to inaccurate quantitative predictions of fibrosis and necroinflammatory activity in the liver.

Comment:

This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

For questions regarding this report please contact customer service at 1-800-788-9223.
### Patient Details
- **DOB:** 01/01/1960
- **Age:** 059/11/15
- **Gender:** F
- **SSN:**
- **Patient ID:**

### Specimen Details
- **Date collected:** 12/16/2019 0000 Local
- **Date received:** 12/16/2019
- **Date entered:** 12/16/2019
- **Date reported:** 12/17/2019 0000 ET

### Physician Details
- **Ordering:**
- **Referring:**
- **ID:**
- **NPI:**

### General Comments & Additional Information
**Clinical Info:** ABNORMAL REPORT

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HCV FibroSure

#### Tests

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**F1 - Portal fibrosis**

**Necroinflammation Activity Score**
- **Score:** 0.23
- **Grade:** A0-A1

#### Analysis:
- **Alpha 2-Macroglobulins, Qn** 280 High mg/dL 110 - 276 01
- **Haptoglobin** 347 High mg/dL 33 - 346 01
- **Apolipoprotein A-1** 210 High mg/dL 116 - 209 01
- **Bilirubin, Total** 1.5 High mg/dL 0.0 - 1.2 01
- **GGT** 61 High IU/L 0 - 40 01
- **ALT (SGPT) P5P** 41 High IU/L 0 - 40 01

#### Interpretations:
Quantitative results of 6 biochemical tests are analyzed using a computational algorithm to provide a quantitative surrogate marker (0.0-1.0) for liver fibrosis (METAVIR F0-F4) and for necroinflammatory activity (METAVIR A0-A3).

**Fibrosis Scoring:**
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- 0.58 - 0.72 = Stage F3 - Bridging fibrosis with many septa
- 0.72 - 0.74 = Stage F3 - F4
- >0.74 = Stage F4 - Cirrhosis

**Necroinflammation Activity Scoring:**
- <0.17 = Grade A0 - No Activity
Looking at the patient study results, we observe a Fibrotest score ranging from 0.29 to 0.36, which corresponds to Grade A1 - Minimal activity. It's essential to note that this test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration. Therefore, the FDA has determined that such clearance or approval is not necessary.

Limitations:

The negative predictive value of a Fibrotest score <0.31 (absence of clinically significant fibrosis) was 85% when compared to liver biopsy in 1,270 HCV infected patients with a 38% prevalence of significant liver fibrosis (F2, 3 or 4). The positive predictive value of a Fibrotest score >0.48 (F2, 3, 4) was 61% in that same patient cohort. HCV FibroSURE is not recommended in patients with Gilbert Disease, acute hemolysis (e.g. HCV ribavirin therapy mediated hemolysis) acute hepatitis of the liver, extra-hepatic cholestasis, transplant patients, and/or renal insufficiency patients. Any of these clinical situations may lead to inaccurate quantitative predictions of fibrosis and necroinflammatory activity in the liver.

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