

**Poster Number: 118 Table 1. FibroScan® Reportable Parameters Presented in E[kPa] and CAP [dB/m] Values**

| Elastography (E[kPa]) | Fibrosis Scale (F0-F4) | Interpretation                 |
|-----------------------|------------------------|--------------------------------|
| <7                    | F0                     | No scarring                    |
| >7 but ≤7.5           | F1                     | Mild fibrosis                  |
| >7.5 but ≤10          | F2                     | Moderate fibrosis              |
| >10 but ≤14           | F3                     | Severe fibrosis                |
| >14                   | F4                     | Cirrhosis or advanced fibrosis |

  

| Controlled Attenuation Parameter (CAP [dB/m])  | Steatosis Grading | Interpretation            |
|--|-------------------|---------------------------|
| Exact cut-off values are not yet defined, but CAP scores above 306 dB/m are strongly correlated to ≥10% hepatic steatosis. | S0                | <5% hepatic steatosis     |
|  | S1                | 5%–33% hepatic steatosis  |
|  | S2                | 34%–66% hepatic steatosis |
|  | S3                | ≥67% hepatic steatosis    |

**Poster Number: 118****Comparing FibroScan® Results Between African-American and Caucasian Populations When Prescreening for Nonalcoholic Liver Disease/Nonalcoholic Steatohepatitis Research Studies**M. Pearson<sup>1</sup>, L. Galitz<sup>1</sup>, M. Fein<sup>1</sup>, L. Rusch<sup>1</sup>, C. A. Dehn<sup>1</sup>, N. McDonald<sup>1</sup><sup>1</sup>High Point Clinical Trials Ctr, High Point, NC, USA**Statement of Purpose, Innovation or Hypothesis:**

The metabolic syndrome (MS) constellation of disorders, including nonalcoholic liver disease/nonalcoholic steatohepatitis (NAFLD/NASH), are known to disparately impact different racial groups. The purpose of our investigation was to assess racial differences in our research population in High Point, North Carolina using a FibroScan® device results to determine parameters that are generally accepted as having a strong correlation to NAFLD/NASH. While liver biopsy remains the current gold standard for diagnosis, Fi-

broScan is well validated and emerging as a surrogate marker in the assessment of NAFLD/NASH.

**Description of Methods and Materials:** In response to the emerging epidemic and drug development opportunities in the NAFLD/NASH arena, High Point Clinical Trials Ctr obtained a FibroScan machine. In addition to using the device for study assessments, we have implemented a prescreening and database building initiative to identify potential participants for clinical trials. This data was leveraged for comparison to known rates of incidence for fatty liver disease among different races. Our study population was from the surrounding metropolitan area and included individuals with risk factors for fatty liver disease including Type II diabetes. The FibroScan machine was used for this prescreening. This device measures tissue elasticity as a rapid, non-invasive, painless test which can be performed by trained research staff in the clinical trial facility. FibroScan reportable parameters presented in E[kPa] and controlled attenuation parameter CAP [dB/m] values. E[kPa] results represent measures of liver stiffness, which is highly correlated to fibrosis. Similarly, CAP scores measured in dB/M are representative of hepatic steatosis. Reference ranges and interpretations are summarized in the attached table.

**Data and Results:** Among these subjects, there were no significant differences in the kPa and CAP score

between African-American males and Caucasian males. Similarly, there was no difference between the females of these two groups. In Black males, CAP scores on average were 290 out of 57 patients; while White males were 301 out of 67 patients; both of which are within the category of S2 to S3 and not very predictive of fatty livers >10%. Also, Black females had CAP scores on average of 307 out of 78 patients, while White females averaged 312 out of 72 patients.

**Interpretation, Conclusion or Significance:** From our results with FibroScan, the diagnosis of NAFLD/NASH in our local population are unexpectedly similar with regards to race. The most commonly-reported potential factors implicated in the racial differences in NAFLD/NASH patients are: lifestyle, IR, distribution of adipose tissue and finally genetics.

---

---