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URINE-BASED METABOLOMICS SIGNATURE TO PREDICT SEVERE COVID-19

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Technology Description

A team of researchers has discovered a urinary metabolite pattern occurring early in COVID-19 disease progression that can predict which patients infected with SARS-CoV-2 are at high risk for respiratory failure or death. This metabolite signature could potentially provide a valuable, life-saving prognostic test to help physicians to manage care or for patient stratification to enable smaller, faster, more efficient clinical trials.

COVID-19 has a remarkably broad range of disease severity with some patients showing no symptoms and others developing severe disease that results in respiratory failure or death. Currently, physicians have no way to predict which patients will proceed on a poor trajectory. This technology addresses that problem with a set of biomarkers that can identify patients likely to develop severe COVID-19. The assay itself is a simple urinalysis performed at the time the patient presents in the hospital and utilizes clinical mass spectrometry instruments that are readily available and routinely used for drug toxicology. The resulting metabolite signature could help physicians identify high-risk patients that require closer monitoring or are most likely to benefit from the scarce supply of antiviral and antibody drugs. In addition, this technology could expedite clinical trials by providing a tool for stratifying patients into subgroups by predicted clinical outcome.

Stage of Research:

- **Modeling** - The inventors discovered the metabolite signature for severe COVID-19 by analyzing urine samples collected from 97 patients on the first day they presented in the hospital; 40% of these patients had severe disease resulting in respiratory failure or death.
- **Validation** – The model was validated using a blinded set of 34 clinical urine samples separate from the original 97 samples. It correctly predicted 8/9 severe outcomes and 13/25 non-severe outcomes.
- **Ongoing** – The inventors continue to evaluate the model and are developing an application-ready LC-MS/MS method compatible with hospital use.

Applications

- **COVID-19 prognostic screening** – identify patients at high risk of severe disease (intubation or death) to determine strategy for care and treatment
- **Clinical trials stratification** – identify sub-groups of patients for efficacy trials
- **Research –** basic studies to elucidate the disease physiology of severe COVID-19

Key Advantages:

- **Early, predictive test –** metabolomics signature is present in urine samples at the time a patient presents in the hospital, potentially enabling:
    - early identification and intervention to avoid ICU admission and associated costs

  - closer monitoring of high risk patients to reduce morbidity and mortality
  - rational allocation of limited doses of expensive therapeutics (e.g., antivirals or antibodies)
  - smaller, faster and more efficient clinical trials
- **Easy to collect and analyze samples:**
  - urine is readily available and can be collected outside of the hospital to reduce exposure risk
  - provides readout of biochemical processes throughout the body
  - rapid biomarker assay utilizing the same clinical mass spectrometry instrumentation that is widely used for routine toxicology and screening for inborn errors of metabolism

Patents: Application filed

Related Web Links: Henderson Profile; Henderson Lab