Can Urine Biomarker Predict the Risk for COVID-19 Severity?

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National Center for Global Health and Medicine

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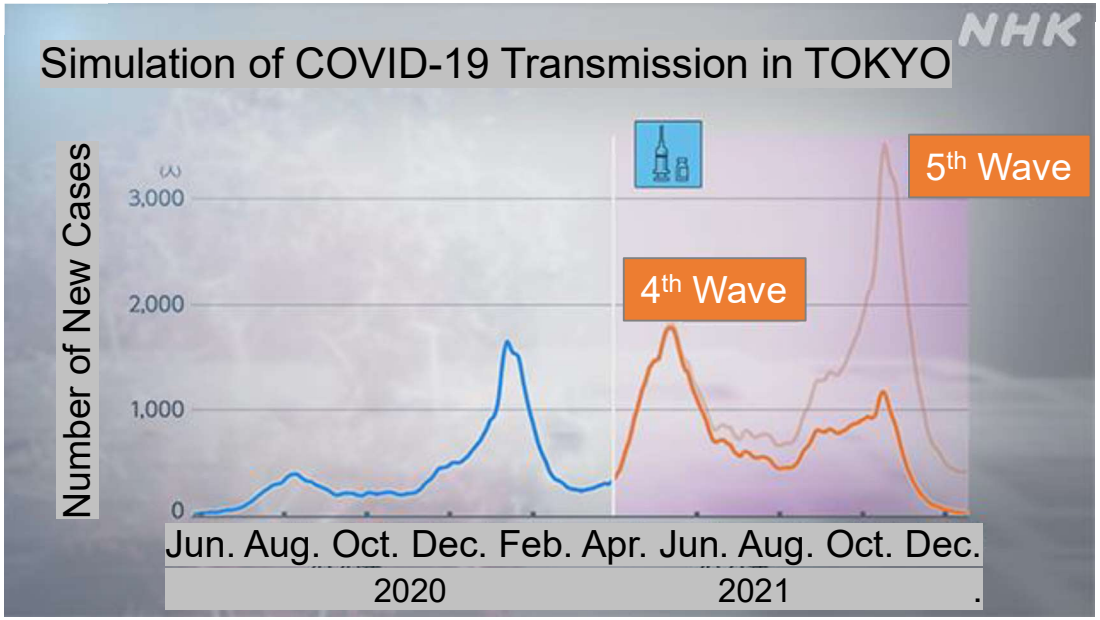
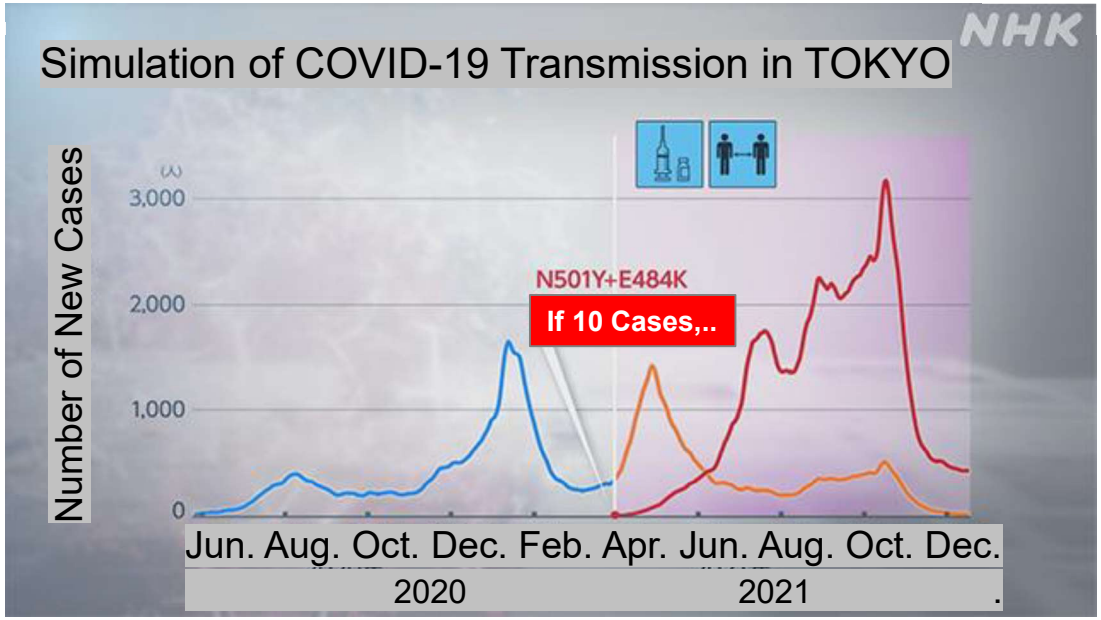
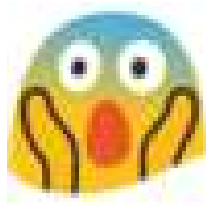
NCGM

Number of Infected & Simulation





Phobia in COVID-19



- Don’t know who will get worsening
  - ✓Mostly Mild Cases
  - ✓Dying in a Week in Severe Cases
  - ✓Pneumonia develops to ARDS

  - ✓It was said Aged, Diabetes, Obesity, etc were Risk.
  - ✓BUT.., it was Not Limited.

- Initially, everyone with COVID-19 shares the same quality of Phobia.
- Diagnosis itself can’t tell your Prognosis.. Dx is just Dx.

Requirements in Pandemic

- Who will get worse?... Triage to Limited Medical Resources.
- Every tests must be Easy to handle.
- Results must be returned On-Site.

- **SpO2..**

Requirements in Pandemic; SpO2

- If SpO2 93%,… Hospitalization
- If SpO2 95%,… Observation

- **SpO2 value is always fluctuating and cannot support decision timely.**

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Evaluation of Coronavirus Disease 2019 Severity Using Urine Biomarkers

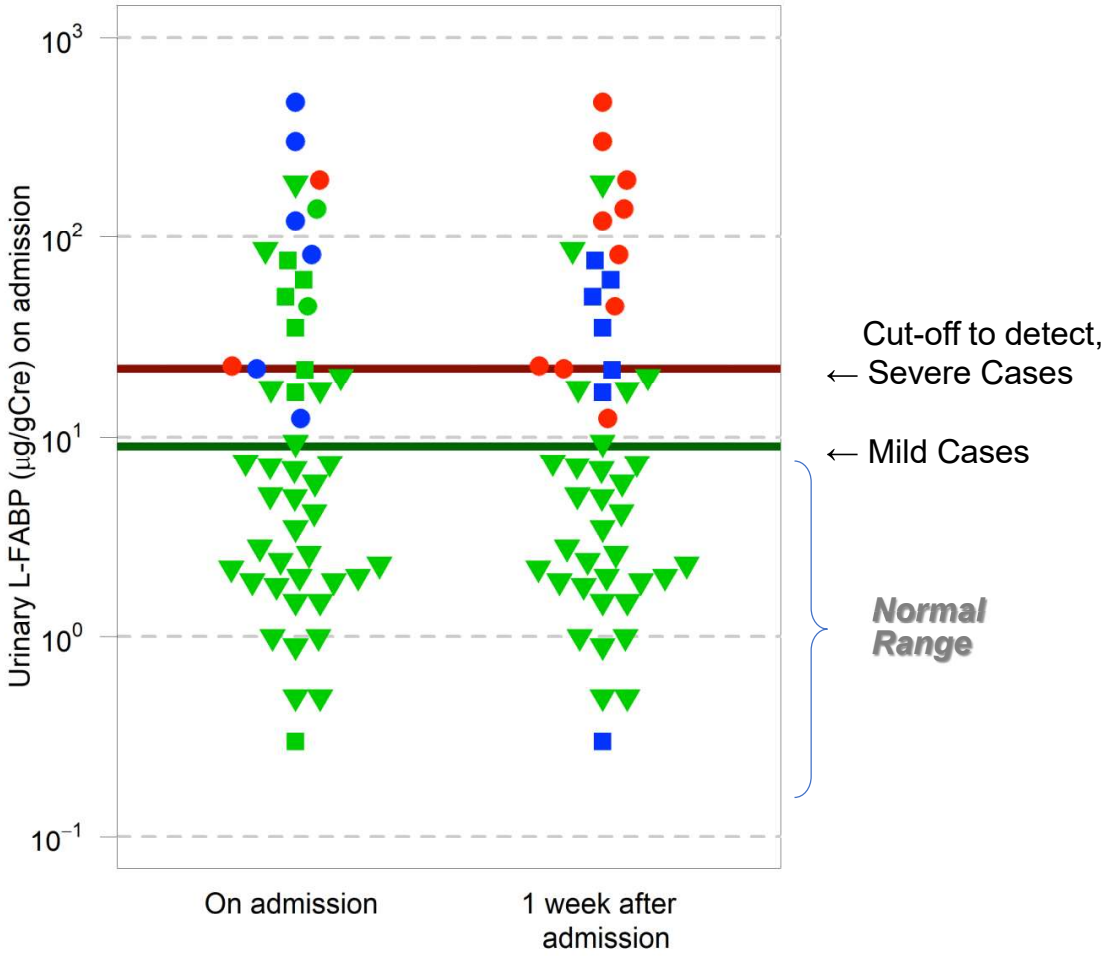
Katagiri D, et al.

Early detection enables appropriate interventions including rapid ICU admission. The study conducted if urine L-FABP can predict clinical severity of SARS-COVID-19.
Single center study by NCGM;**58** were included. They were assigned to the severe (12), moderate (13), mild group (33).
Severe vs. Moderate+Mild in L-FABP was 22ng/gCr (≈10ng/dL).
AUC-ROC 91.8% (specificity 84.6, sensitivity 90%).

Evaluating urinary L-FABP may allow determination of patients with active cytokines and recognition of patients likely to become critically ill and requiring careful observation and early intervention.

Shape of symbols: Severity at 1 week after admission
● Severe ■ Moderate ▼ Mild
Color of symbols: Severity at each time point
■ Severe ■ Moderate ■ Mild

Progression of Severity and L-FABP on Admission



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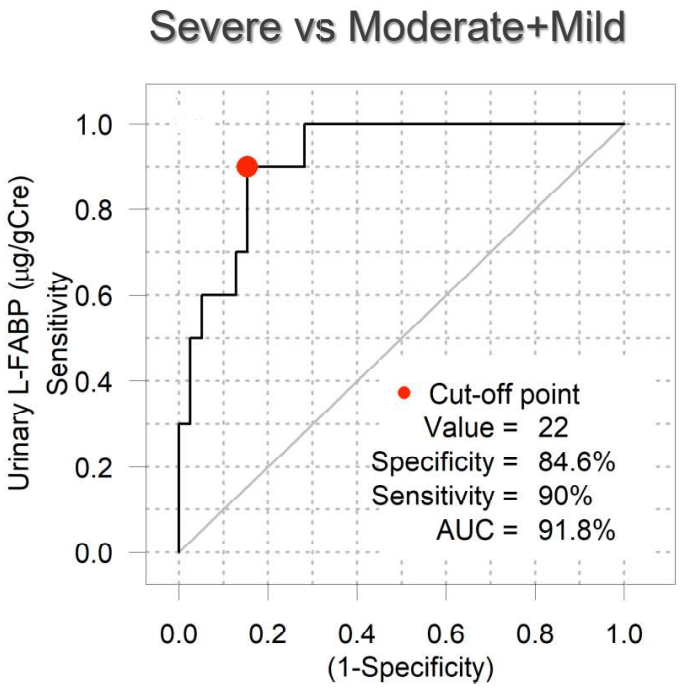
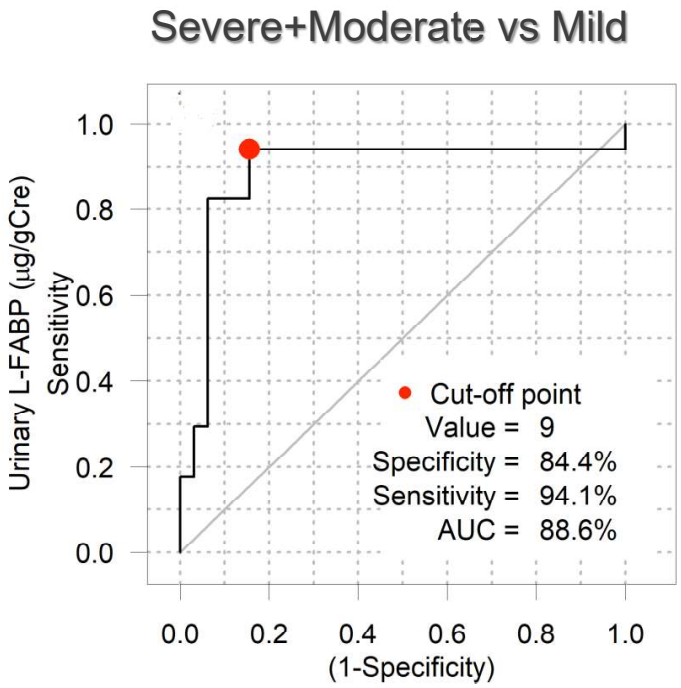
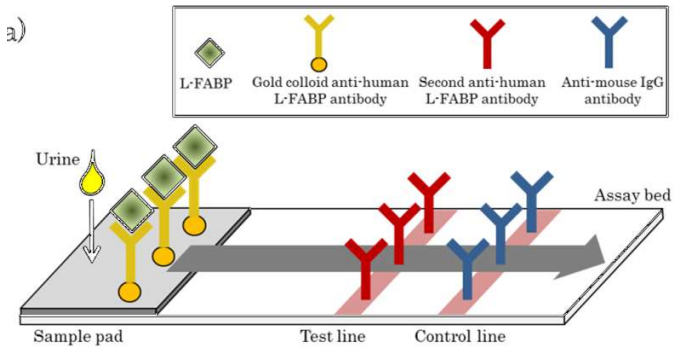
ROC≈90%



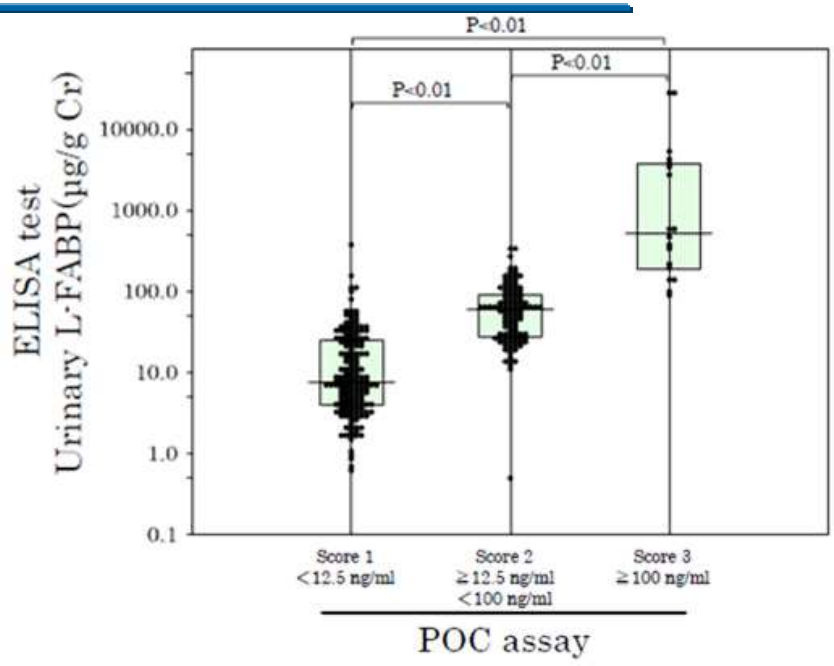


Corr.; Urine L-FABP　POC vs. ELISA



新型コロナ 尿検査で重症化を予測できる可能性 研究グループ

2020年8月4日 14時57分　新型コロナウイルス



Control Line C

Test Line T

CKD　106 cases、ICU 29 cases
Score Match Rate≧90%

Renal Replacement Therapy (3) 26, 2017

Urine L-FABP POC Test Kit

Risk Stratification of COVID-19 Using Urine Biomarkers

ClinicalTrials.gov Identifier: NCT04681040

Recruitment Status : Recruiting
First Posted : December 23, 2020
Last Update Posted : December 28, 2020

See Contacts and Locations

Sponsor:
National Center for Global Health and Medicine, Japan

Information provided by (Responsible Party):
Eisei Noiri, National Center for Global Health and Medicine, Japan

Study Description

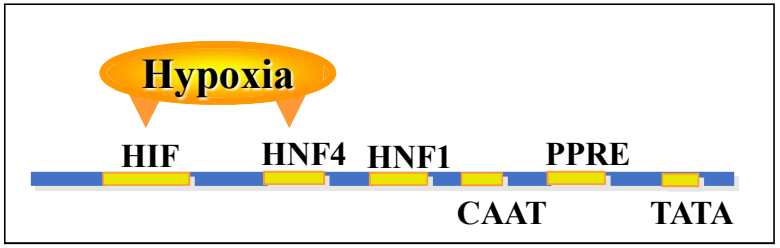
Go to

Brief Summary:
Coronavirus disease 2019 (**COVID-19**) is caused by **severe acute respiratory syndrome coronavirus 2** (**SARS-CoV-2**) and in infected patients, it produces symptoms which range from completely asymptomatic to those expressing severe illness. Early recognition of those developing severe manifestations allows for rapid and appropriate intervention, including admission to intensive care unit and intensive care therapy, such as mechanical ventilation. A current problem is that only limited data exist predicting the clinical course of **COVID-19.** This study will determine whether non-invasive urinalysis is useful in assessing and predicting the severity or clinical course of patients with **COVID-19.**

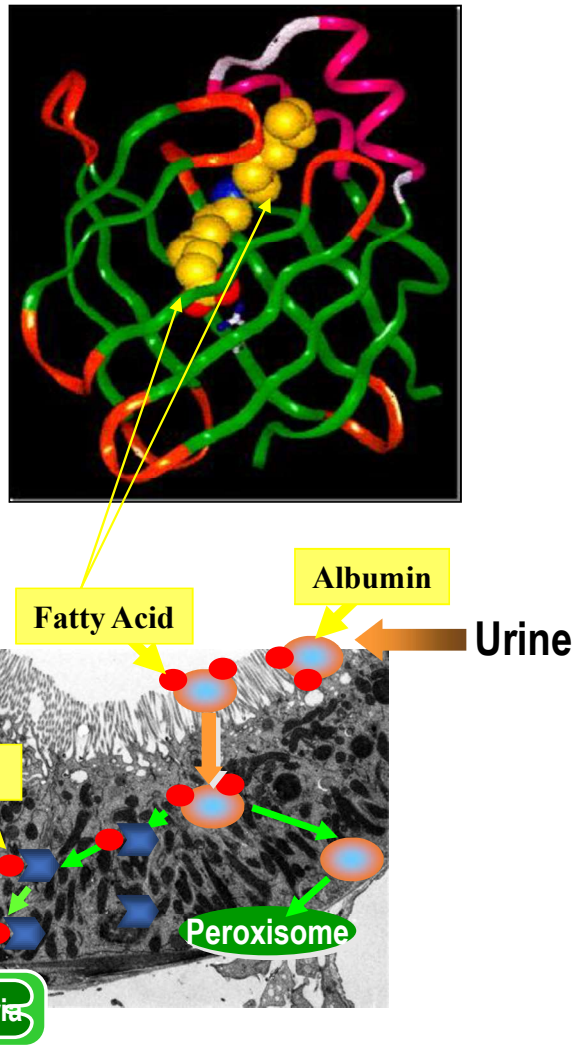
Condition or disease
Covid19
Urine
Biomarker
Acute Respiratory Failure With Hypoxia

Molecular Mechanism

- Kidney Receives 20% of cardiac output.
- Kidney is sensitive to oxygen level and determine Hgb level.
- L-FABP is 14kDa and escort protein for energy recycling.
- L-FABP predominantly express at proximal tubules where the most oxygen sensitive part.
- If hypoxic, the expression level of L-FABP increases through promoter region.
- The level of urinary L-FABP increase; L-FABP alert is utilized to monitor the risk of COVID-19.



Promoter of L-FABP



J Am Soc Nephrol (18) 2894, 2007

Accountability

- Urinary L-FABP derived from Kidney (proximal tubular cells) with the increase under hypoxic condition and under higher oxidative stress.
- Urine POC is easy to handle and applicable to any situation.
- Urine is virtually negative of COVID-19 by LAMP test (n=80).
- Higher L-FABP level reflect higher hypoxic condition in COVID-19 pneumonia and susceptibility to ARDS.
- Lower L-FABP certify better prognosis.

Solution

- Initially stay home or room after COVID-19 diagnosis.
- Urine L-FABP test within 2 days for Risk Evaluation.
- Medical resources should focus on the higher L-FABP subjects.

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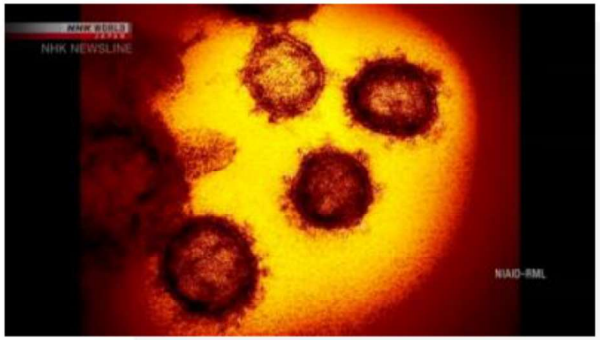
Clinical urine tests may predict COVID-19 progress

#Japan #Coronavirus 2 hours ago



NHK has learned that a group of researchers in Japan will conduct a clinical study using urine samples from COVID-19 patients to predict whether their conditions will become serious.

Researchers at the National Center for Global Health and Medicine will collect urine samples from about 500 patients who are at hospitals or in quarantine at accommodations. They will then examine the amount of a protein called L-FABP contained in those samples.

The researchers say their recent studies have shown that when the level of L-FABP is higher than normal, the risk of symptoms worsening is more than eight times higher.

The patients will use test kits to conduct the urine tests by themselves, soon after they have been admitted to hospitals or put into quarantine. They will then use their smartphones to send photos of their test kits to the center. Medical doctors will make a determination about the test results.

The researchers say they will call for cooperation from local governments and medical institutions, as their aim is to start the clinical study this month.

Katagiri Daisuke is a doctor at the center. He says he believes that patients will be able to be hospitalized more smoothly when necessary, if the urine tests are put into practical use.

#Japan #Coronavirus

Thank you for your attention

Collaborators
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References

1. Am J Physiol Renal Physiol (296) F669, 2009
2. J Am Soc Nephrol (18) 2894, 2007
3. Renal Replacement Therapy (3) 26, 2017
4. Chap 12: Kala Azar in South Asia 2ndEdition, *Springer Verlag*, 2017

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