Procalcitonin for the Evaluation and Antibiotic Management of Suspected Lower Respiratory Tract Infections and Sepsis

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Microbiology Devices Panel Meeting
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The Focus of Today's Meeting: bioMérieux, Inc. 510(k) for Expanding the Current Intended Use for Procalcitonin

Current Intended Use

VIDAS® B•R•A•H•M•S PCT™ (PCT) is an automated test for use on the instruments of the VIDAS® family for the determination of human procalcitonin in human serum or plasma (lithium heparinate) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. Used in conjunction with other laboratory findings and clinical assessments, VIDAS® B•R•A•H•M•S PCT™ is intended for use as follows:

- To aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock,
- To aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission, using a change in PCT level over time.

Modified Intended Use

VIDAS® B•R•A•H•M•S PCT™ (PCT) is an automated test for use on the instruments of the VIDAS® family for the determination of human procalcitonin in human serum or plasma (lithium heparinate) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. Used in conjunction with other laboratory findings and clinical assessments, VIDAS® B•R•A•H•M•S PCT™ is intended for use as follows:

- To aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock,
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- To aid in decision making on antibiotic therapy for inpatients or outpatients, with suspected or confirmed lower respiratory tract infections (LRTI) defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD),
- To aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis.

Validation of New Claims

- Is the submitted evidence sufficient to make a determination of safety and effectiveness for the addition of these new claims:

LRTI

- As an aid in antibiotic initiation in the setting of lower respiratory tract infection;
- As an aid for antibiotic discontinuation in the setting of lower respiratory tract infection;

Sepsis

- As an aid in the discontinuation of antibiotics for patients with sepsis.

Clinical Use of Procalcitonin

- 10+ years after the first FDA clearance for sepsis…
  - Google: ~400+K hits
  - PubMed: > 3000 citations
  - ID Week 2016: 33 Citations, special symposium
- Despite these efforts, the clinical utility of PCT remains a subject of diverging opinions
- PCT is an area of active investigation
  - e.g., ProACT and TRAP/LRTI studies

Topics for Discussion

- The current meeting reflects why opinions may be diverging and discussion is needed:
  - The expansion of the claims for PCT is significant and potentially impacts the care of numerous patients
  - Using a meta-analysis to establish new claims is atypical; is this approach sufficient to determine safety and effectiveness?
  - How much uncertainty persists following review of published studies regarding the proposed conditions of use and the proposed diagnostic algorithm?

Advisory Panel Meeting Agenda

- Presentations, comments and concerns related to the sponsor's meta-analyses of published data
- Open public comments regarding PCT-guided management
- Panel discussion of available evidence
- Panel Question: Is PCT-guided management safe and effective for the proposed use?

Agenda

8:30 a.m.	ARLG Presentation: Dr. Ebbing Lautenbach
9:00 a.m.	bioMérieux Presentation
10:15 a.m.	Break
10:30 a.m.	FDA Presentations: Dr. Brittany Goldberg and Dr. Qin Li
11:45 a.m.	Lunch
12:45 p.m.	Open Public Hearing
1:45 p.m.	Panel Deliberations
2:45 p.m.	Break
3:00 p.m.	FDA Questions
5:00 p.m.	Chair closing remarks
5:10 p.m.	Adjournment

Thank you…

- The sponsor, bioMérieux, Inc.
- The committee and the consultants to the committee for participating in this important meeting
- And all others who have contributed…