

**FDA Executive Summary:
Errata**

Prepared for the
November 10, 2016 meeting of the
Microbiology Devices Panel of the
Medical Devices Advisory Committee

*Discussion and Recommendations for the Application of Procalcitonin
to the Evaluation and Management of Suspected Lower Respiratory
Tract Infections and Sepsis*

Gaithersburg, Maryland

1. Throughout the executive summary, FDA used the term ‘de-escalation’ for the sepsis claim. However, bioMérieux is seeking a claim for antibiotic discontinuation to be more precise in their labeling and exclude dose reductions, changes to targeted antibiotic therapy or other antibiotic adjustments.
2. In Table 1 below, the median duration of antibiotics in days for inpatients was incorrectly stated to be -3.26 (-3.72, -2.79). The correct median duration of antibiotics for inpatients is -3.07 (-3.54, -2.60). For outpatients, the median duration in days was incorrectly stated to be -1.75 (-2.28, -1.21). The correct median duration of antibiotics is -1.68 (-2.21, -1.14).
3. On page 18 of the executive summary, it is stated that there were no U.S. clinical trial sites in sepsis meta-analyses. However, one of the three clinical trial sites from the Stolz et al. study was in the United States. (Stolz et al., 2009)

Table 1^a

LRTI Patient-Level Data Subgroup Analysis	Standard Therapy	PCT-guided Therapy	Adjusted OR or Difference (95% CI) ^b
Overall	1606	1536	
Initiation of antibiotics, n(%)	1420 (88.7)	1096 (71.4%)	0.27 (0.22, 0.33)
Duration of antibiotics in days, median (IQR) ^c	10 (7, 12)	7 (4, 10)	-2.9 (-3.3, -2.5)
CAP	1028	999	
Initiation of Antibiotics n(%)	1019 (99%)	898 (90%)	0.07 (0.03, 0.14)
Duration of Antibiotics in days median (IQR)	10 (8, 14)	7 (5, 10)	-3.34 (-3.79, -2.88)
Bronchitis	282	249	
Initiation of Antibiotics n(%)	185 (66%)	61 (25%)	0.15 (0.10, 0.23)
Duration of Antibiotics in days median (IQR)	7 (5, 8)	7 (4, 9)	-0.38 (-1.21, 0.46)
AECOPD	296	288	
Initiation of Antibiotics n(%)	216 (73%)	137 (48%)	0.32 (0.23, 0.46)
Duration of Antibiotics in days median (IQR)	8 (6, 10)	6 (3, 9)	-1.58 (-2.33, -0.82)
Inpatients	1139	1106	
Initiation of Antibiotics n(%)	1039 (91.2%)	881 (79.7%)	0.35 (0.27, 0.46)
Duration of Antibiotics in days median (IQR)	10 (8, 14)	7 (4, 10)	-3.07 (-3.54, -2.60) -3.26 (-3.72, -2.79)
Outpatients	467	430	
Initiation of Antibiotics n(%)	381 (81.6%)	215 (50%)	0.13 (0.09, 0.19)
Duration of Antibiotics in days median (IQR)	7 (6, 10)	6 (4, 8)	-1.68 (-2.21, -1.14) -1.75 (-2.28, -1.21)

^a Modified table from Table 15, Figures 11 and 12 in the bioMérieux executive summary and Section 26.3 of 'Clinical Performance Characteristics.'

^b Multivariable hierarchical model adjusted for age and diagnosis and trial as a random effect; For the subgroup by type of LRTI, diagnosis was not included in the model.

^c Duration includes subjects who were initiated on antibiotics

Reference:

Stolz, D., Smyrnios, N., Eggimann, P., Pargger, H., Thakkar, N., Siegemund, M., . . . Tamm, M. (2009). Procalcitonin for reduced antibiotic exposure in ventilator-associated pneumonia: a randomised study. *Eur Respir J*, 34(6), 1364-1375. doi: 10.1183/09031936.00053209