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ORIGINAL ARTICLE

Direct MS-Based Bacterial Identification of Blood Cultures. Comparison of an In-House TritonX-Protocol with Bruker-Sepsityper™

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SUMMARY

Background: **Matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF MS) revolutionized the identification of bacterial pathogens. Especially in time sensitive situations, such as blood stream infections this technique significantly reduced the turn-around times. The direct bacterial extraction of positive blood culture bottles and consecutive MALDI-TOF MS-based identification is able to provide the clinician actionable health information earlier than conventional microbiological identification techniques such as Vitek 2™ (bioMérieux).**

Methods: **We developed an in-house extraction method for bacterial identification in blood culture flasks and compared this with the commercially available Bruker Sepsityper™ kit. First, 40 clinical samples were processed with both sample preparation methods. Second, diagnostic performance as well as handling, assay time and extraction costs were compared. Finally, all results were validated by identification of the subcultured isolates from agar plates.**

Results: **Even though we obtained slightly higher scores with the Sepsityper™ kit, it was possible to identify 97.5% of all isolates by Bruker Sepsityper™ kit and 92.5% by using the in-house assay with the standard cutoff value. By applying modified acceptance criteria, we were able to identify 100% by Bruker Sepsityper™ kit and 97.5% of all isolates with the in-house assay. Most importantly, no misidentification occurred. The comparison of the extraction costs revealed, that the in-house assay is considerably less expensive (0.01€ vs. 8.62€) and offers shorter hands-on time (19 vs. 30 minutes).**

Conclusions: **We have developed and validated an in-house extraction method with comparable performance to the Bruker Sepsityper™ kit that reduces unit test cost and evaluation time leading to a cost benefit of 63.24% in this scenario.**

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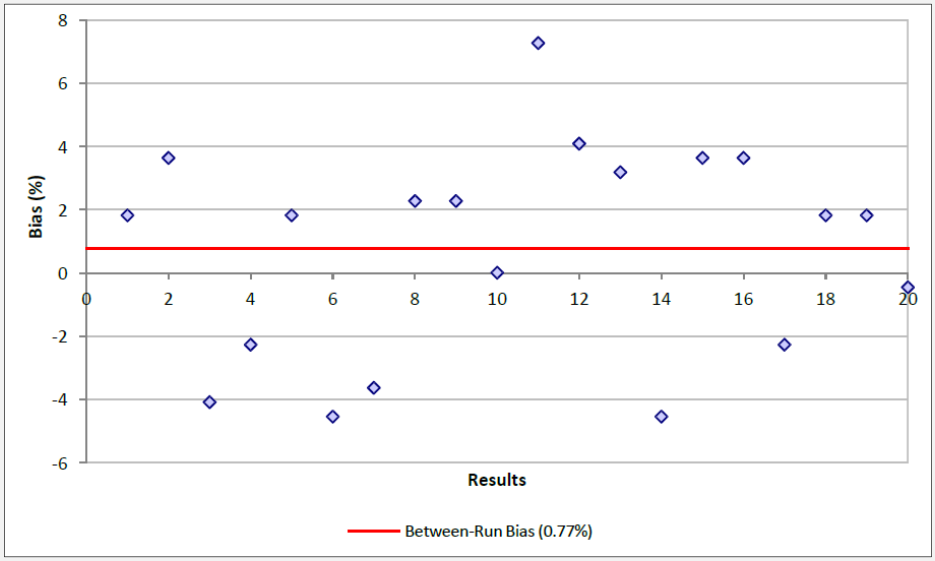
Supplementary Tables and Figures.

Precision & Bias (5 x 4 Model)

Data 1 - ATCC *E. coli.*



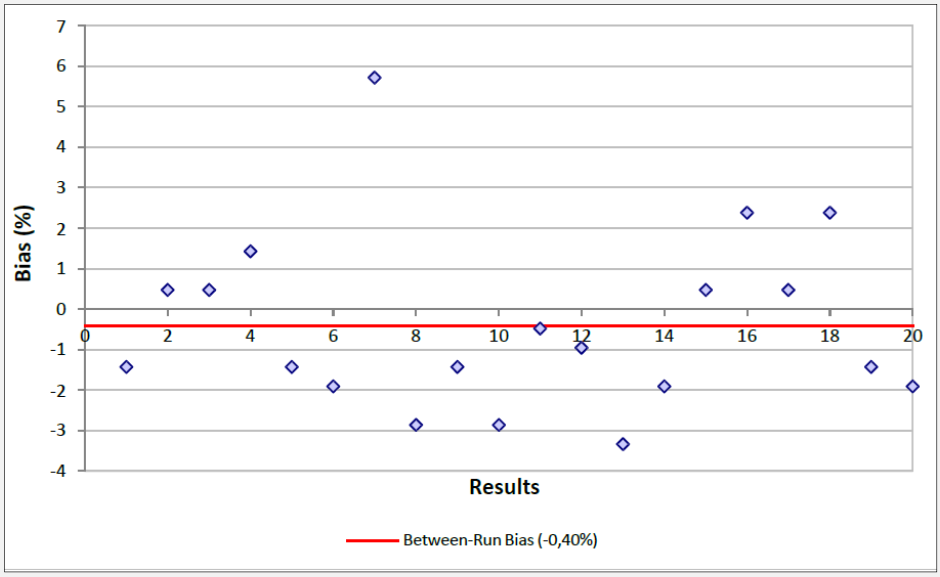
STATISTICS				
Within-Run				
Run	Day 1	Day 2	Day 3	Day 4
Target Value	2.2	2.2	2.2	2.2
Mean	2.2	2.2	2.3	2.2
Standard Deviation	0.1	0.1	0.1	0.1
CV (%)	3.22%	3.25%	4.26%	2.27%
Bias	0.18%	-0.73%	2.73%	0.91%
Bias Range	-0.73% up to 2.73%			
Allowable Bias	± 10.00%			
Mean CV (%)	3.25%			
Allowable CV (%)	10.00%			
Pass/Fail?	Pass			

Between-Run	
Target Value	2.2
Mean	2.2
Standard Deviation	0.1
Bias	0.77%
Allowable Bias	± 10.00%
CV (%)	3.32%
Allowable CV (%)	10.00%
Pass/Fail?	Pass

SPECIFICATIONS	
Instrument	**Bruker MicroflexLT**
Units	**-**
Specimen Type	**-**
Reagent Lot	**-**
Control Lot	**-**
Period	**July 3rd, 2017 through July 6th, 2017**
Comment	**-**

Precision & Bias (5 x 4 Model)

Data 2 - ATCC S. aureus.



STATISTICS				
Within-Run				
Run	**Day 1**	**Day 2**	**Day 3**	**Day 4**
Target Value	**2.1**	**2.1**	**2.1**	**2.1**
Mean	**2.1**	**2.1**	**2.1**	**2.1**
Standard Deviation	**0.027**	**0.1**	**0.030**	**0.043**
CV (%)	**1.28%**	**3.64%**	**1.47%**	**2.02%**
Bias	**-0.10%**	**-0.67%**	**-1.24%**	**0.38%**
Bias Range	**-1.24% up to 0.38%**			
Allowable Bias	**± 10.00%**			
Mean CV (%)	**2.10%**			
Allowable CV (%)	**10.00%**			
Pass/Fail?	**Pass**			

Between-Run	
Target Value	**2.1**
Mean	**2.1**
Standard Deviation	**0.046**
Bias	**-0.40%**
Allowable Bias	**± 10.00%**
CV (%)	**2.20%**
Allowable CV (%)	**10.00%**
Pass/Fail?	**Pass**

SPECIFICATIONS	
Instrument	**Bruker MicroflexLT**
Units	**-**
Specimen Type	**-**
Reagent Lot	**-**
Control Lot	**-**
Period	**July 3rd, 2017 throough July 6th, 2017**
Comment	**-**