

Conclusion. In our study, LAMP assay was found to be a promising tool for the diagnosis of Tubercular Lymphadenitis and could be used for rapid and cost-effective diagnosis of Tubercular Lymphadenitis in resource-limited settings.

Table 1: Diagnostic accuracy of LoopAMP™ with and without CRS

Method	Performance % (95% CI)			
	Sensitivity	Specificity	PPV	NPV
LoopAMP™ (Smear as standard)	100% (39.8% to 100%)	69.7% (57.2% to 80.4%)	16.7% (12.2% to 22.4%)	100%
LoopAMP™ (CRS as reference standard)	100% (85.8% to 100%)	100% (92.3% to 100%)	100%	100%

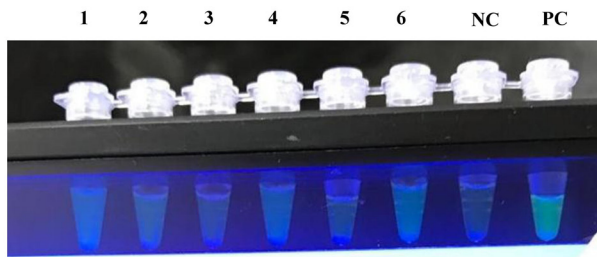


Figure : Visual detection of LAMP assay under UV light. From left to right, tubes 5 is negative, and tubes 1,2,3,4 and 6 are positive.

Table 2 : Diagnostic performance of LoopAMP™ with CRS taken as gold standard (n=70)

LoopAMP™	CRS (gold standard)		Performance (%), (95% CI)			
	Positive	Negative	Sensitivity	Specificity	PPV	NPV
Positive	24	0	100% (85.8% to 100%)	100% (92.3% to 100%)	100%	100%
Negative	0	46				
Total	24	46				

Table 3: Diagnostic performance of LoopAMP™ with smear taken as gold standard (n=70)

LoopAMP™	Smear (gold standard)		Performance (%), (95% CI)			
	Positive	Negative	Sensitivity	Specificity	PPV	NPV
Positive	4	20	100% (39.8% to 100%)	69.7% (57.2% to 80.4%)	16.7% (12.2% to 22.4%)	100%
Negative	0	46				
Total	4	66				

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2157. Evaluation of the Utility of the MRSA Nasal PCR Assay in a Community Healthcare System

Athena L. V. Hobbs, PharmD, BCIDP¹; Stephen Turner, PharmD¹; Bhavyata Parag, PharmD²; Katherine M. Shea, PharmD, BCIDP³; Nathan Seligson, PharmD⁴; ¹Baptist Memorial Hospital-Memphis, Memphis, Tennessee; ²Houston Methodist Clear Lake Hospital, Houston, Texas; ³Cardinal Health, Austin, Texas; ⁴University of Florida College of Pharmacy, Gainesville, Florida

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Background. The MRSA nasal PCR assay is a rapid, noninvasive test that has demonstrated a strong negative predictive value (NPV), as high as 99%, for ruling out MRSA pneumonia. These findings are based primarily on literature from large academic centers, which have evaluated both the positive predictive value (PPV) and NPV of MRSA nasal PCR assays. Investigators sought to assess the NPV of the MRSA nasal PCR assay to rule out MRSA pneumonia within a community healthcare system. To the best of our knowledge, this is the largest study from a community hospital and the only study from a community healthcare system for the utilization of a nasal PCR assay to rule out MRSA pneumonia.

Methods. This is a multicenter, retrospective study of adult patients with both an MRSA nasal PCR assay and positive respiratory culture (sputum, bronchoalveolar lavage, or endotracheal aspirate). Data were collected from September 2014 through August 2015 at three community hospitals (bed size ranging from 328 to 706) across two states within a healthcare system. The study was approved by the Baptist Memorial Hospital Institutional Review Board. PPV and NPV 95% confidence intervals (95% CI) were calculated as previously described in the literature.

Results. A total of 808 patients were included in the analysis across the three hospitals. The total incidence of MRSA in positive sputum samples was 14.9% across the three facilities. Our study demonstrated an overall NPV of 95.1% (93.2, 96.6%) and a PPV of 65.9% (95% CI 57.2, 73.9%). The high NPV was retained despite unit type, resulting in 94.9% (95% CI 92.7, 96.6%), 96.3% (95% CI 90.8, 99.0%), and 94.7% (95% CI 74.0, 99.9%) for the intensive care units (ICU), medical-surgical units, and the emergency department, respectively (Table 1).

Conclusion. We concluded that the high NPV of a negative MRSA nasal PCR assay to rule out MRSA pneumonia persisted within a community hospital system. With the results of our study, we plan to utilize institution-specific data along with previously published literature to encourage earlier discontinuation of anti-MRSA antibiotics in patients being treated for pneumonia with negative MRSA nasal PCR assays. Our study demonstrates the validity of the assay in the large community hospital setting with similar findings to studies at large academic institutions.

Table 1: Results

	NPV	95%CI	PPV	95%CI
Overall	95.1%	93.2, 96.6%	65.9%	57.2, 73.9%
Intensive Care Units	94.9%	92.7, 96.6%	67.3%	57.4, 76.2%
Medical-surgical Units	96.3%	90.8, 99.0%	58.3%	36.6, 77.9%
Emergency Department	94.7%	74.0, 99.9%	75.0%	19.4, 99.4%

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2158. Cost-Effectiveness and Budget Impact of a Point-of-Care Nucleic Acid Amplification Test for Diagnosis of Group A Streptococcal Pharyngitis in the United States

James Karichu, MPH, PhD¹; Mindy Cheng, MS, PhD¹; Joanna Sickler, MPH, MBA²; Julie Munakata³; S. Pinar Bilir³; Eliza Kruger³; Roche Molecular Diagnostics, Inc., Pleasanton, California; ²Roche Molecular Systems, Inc., Pleasanton, California; ³IQVIA, San Francisco, California

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Background. Group A streptococcal (GAS) pharyngitis is common in the United States (US). Each year, approximately 12 million people seek medical care for pharyngitis, accounting for ~2% of ambulatory care visits. The gold standard method for diagnosing GAS is culture. However, because culture is time intensive, rapid antigen detection tests (RADTs), with or without culture confirmation, are commonly used. Although RADTs provide results quickly, test sensitivity has been shown to be sub-optimal, which can lead to inappropriate treatment decisions. Recently, highly sensitive point-of-care nucleic acid amplification tests (POC NAAT), such as the cobas[®] Liat[®] System, have emerged. The objective of this study was to evaluate the cost-effectiveness (CE) and budget impact (BI) of adopting POC NAAT compared with RADT+culture confirmation to diagnose GAS pharyngitis from the US third-party payer perspective.

Methods. A decision-tree economic model was developed in Microsoft Excel to quantify costs and clinical outcomes associated with POC NAAT and RADT+culture over a one-year period. All model inputs were derived from published literature and public databases. Model outputs included costs and clinical effects measured as quality-adjusted life days (QALDs) lost. One-way and probabilistic sensitivity analyses were performed to assess the impact of uncertainty on results.

Results. CE analysis showed that POC NAAT would cost \$44 per patient compared with \$78 with RADT+ culture. POC NAAT was associated with fewer QALDs lost relative to RADT+ culture. Therefore, POC NAAT may be considered the “dominant” strategy (i.e., lower costs and higher effectiveness). Findings were robust in sensitivity analyses. BI analysis showed that adopting POC NAAT for diagnosis of GAS could yield cost-savings of 0.3% vs. current budget over 3 years. This is due to savings associated with testing, GAS-related complications, antibiotic treatment and treatment-associated complication costs.

Conclusion. Results suggest that adopting POC NAAT to diagnose GAS would be considered cost-effective and yield cost-savings for US payers relative to RADT+culture. Access to POC NAAT would be important to optimize appropriate GAS diagnosis and treatment decisions.

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2159. Accurate Carbapenem Susceptibility Testing Within 5-6 Hours

Eric Stern, PhD¹; Kelly Flentie, PhD¹; Benjamin Spears, PhD²; Felicia Chen, MS²; Kayla DaPonte, MLS(ASCP)CM²; Kristin Baker, PhD²; Ariela Esmurria, BS²; Fred Floyd, BS²; Jamie Liu, BS²; Vamsee Pasangulapati, MS²; Niall Plunkett, BS²; Derek Puff, PhD²; Nate Purmort, MS¹; Patrick Reilly, BS²; Andy Reynolds, BS²; Hemal Shah, BS²; Mark Somers, BS²; Aleksandar Vacic, PhD²; Matthew Briscoe, BS²; Kenny Varner, MS²; Alan Chao, PhD²; Noah Miller, Pursuing BS²; Meghan Quon, Pursuing BS²; Jun Jie Chen, Pursuing BS²; Mark Clancy, Pursuing BS²; Alana Persing, Pursuing BS²; Mary Jane Ferraro, PhD, MPH³; David C. Rosenberg, MD³; ¹SeLux Diagnostics, Jamaica Plain, Massachusetts; ²Selux Diagnostics, Charlestown, Massachusetts; ³Massachusetts General Hospital, Boston, Massachusetts

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Background. Patients infected with multi-drug-resistant (MDR) pathogens may experience long delays to targeted therapies due to the incomplete antimicrobial menus and/or breakpoints tested on current commercial antimicrobial susceptibility testing (AST) systems. Detection of carbapenem resistance poses a challenge to rapid, accurate, minimum inhibitory concentrations (MIC) determinations because some

resistant organisms may be inhibited by a carbapenem antibiotic until sufficient carbapenemase production has been achieved and traditional AST platforms must wait to make MIC calls. More accurate carbapenem MICs can be determined by implementing a carbapenemase test alongside rapid AST.

Methods. We demonstrate a novel, proprietary test to detect carbapenemase production that enables rapid MIC testing for carbapenem antibiotics. The test is processed in parallel with the Selux next-generation phenotyping (NGP) AST method, enabling rapid, <6-hour, accurate MIC determinations. The carbapenemase assay utilizes high concentrations of intact bacteria. After 3 hours of incubation, a fluorescent pH indicator is read spectroscopically. The solution pH is lowered by carbapenemase-mediated imipenem degradation and is indicative of enzyme activity.

Results. This assay accurately identifies carbapenemases across multiple enzyme classes and bacterial species. Figure 1 shows the accuracy and speed of NGP AST at determining MICs for representative isolates from the FDA-CDC antimicrobial resistance bank compared with results from overnight broth microdilution (BMD). To date, over 100 challenge strains of *Enterobacteriaceae*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii* have been tested with no very major errors and an average time-to-result of 5.3 hours.

Conclusion. By incorporating a rapid, on-board carbapenemase activity assay, the NGP AST platform rapidly delivers accurate carbapenem results. Combined with NGP's comprehensive antibiotic menus, this platform will therefore ensure prompt delivery of personalized antibiotic therapies for all patients, including those infected with MDROs, and enable streamlined antibiotic stewardship coordination.

Isolate	Carbapenemase	Overnight BMD MIC	NGP IMP MIC	NGP Time to Result (hrs)
<i>E cloacae</i> AR 154	VIM	≥ 8	8	5
<i>E cloacae</i> AR 161	IMP	4	8	5
<i>E cloacae</i> AR 32	KPC	2	8	5
<i>E cloacae</i> AR 38	NDM	≥ 8	≥ 8	5
<i>E coli</i> AR 61	KPC	4	4	5
<i>E coli</i> AR 69	NDM	8	8	5
<i>K aerogenes</i> AR 7	None	0.5	0.5	5
<i>K pneumoniae</i> AR 153	NDM	≥ 8	≥ 8	5
<i>K pneumoniae</i> AR 361	KPC	8	8	5
<i>K pneumoniae</i> AR 504	OXA	4	4	5
<i>A baumannii</i> AR 52	OXA	8	≥ 8	5
<i>K pneumoniae</i> ATCC 700603	None	< 0.12	< 0.12	5
<i>P aeruginosa</i> AR 54	VIM	≥ 8	≥ 8	6

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2160. Performance of the Cepheid Rapid PCR Test for Patient Screening and Association with Efficacy of Suvratoxumab, A Novel Anti-*Staphylococcus aureus* Monoclonal Antibody, During the Phase 2 SAATELLITE study

Alexey Ruzin, PhD¹; Li Yu, PhD²; Olivier Barraud³; Bruno François, Physician⁴; Miguel Sánchez García, MD, PhD⁵; Philippe Eggimann, MD⁶; Pierre-François Dequin, MD PhD⁷; Pierre-François Laterre, MD⁸; Vincent Huberlant, MD⁹; Lucia Viña, MD¹⁰; Thierry Boulain, MD¹¹; Cédric Bretonnière, MD, PhD¹²; Jérôme Pugin, MD¹³; José Trenado Álvarez, MD, PhD¹⁴; Ana Catalina Hernandez Padilla¹⁵; Julie Vignaud⁴; Drieke Vandamme, PhD⁴; Omar Ali, PhD⁴; Kathryn Shoemaker, MS¹⁶; Susan Colbert, RN, BSN; Terramika Bellamy, MS¹⁶; Bret R. Sellman, PhD¹; Michael McCarthy, MD¹⁷; Hasan S. Jafri, MD¹; Mark T. Esser, PhD¹; AstraZeneca, Gaithersburg, Maryland; AstraZeneca, Gaithersburg, Maryland; Inserm / Université Limoges / CHU Limoges, Limoges, Limousin, France; CHU Limoges, Limoges, Limousin, France; Hospital Clinico San Carlos, Madrid, Spain; University Hospital and University of Lausanne - Switzerland, Lausanne, Vaud, Switzerland; University of Tours, Tours, Centre, France; St Luc University Hospital, University of Louvain, Brussels Hoofdstedelijk Gewest, Belgium; Centre Hospitalier Jolimont-Lobbès, Jolimont-Lobbès, Hainaut, Belgium; Hospital universitario central de Asturias, Oviedo, Asturias, Spain; Centre Hospitalier Régional d'Orléans, Orléans, Centre, France; Institut du Thorax - CHU Nantes, Nantes, Pays de la Loire, France; Adult Intensive Care, Geneva University Hospitals, Geneva, Geneva, Switzerland; Hospital Universitari Mutua Terrassa, Terrassa, Catalonia, Spain; Centre Hospitalier Universitaire de Limoges, Limoges, Limousin, France; Director, Gaithersburg, Maryland; MedImmune, Gaithersburg, Maryland

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Background. Patients with lower airway *Staphylococcus aureus* (SA) colonization are at great risk (> 20%) of early-onset ventilator-associated pneumonia (VAP). Thus, a rapid test is required to identify patients at risk. Suvratoxumab (formerly MEDI4893) is a human monoclonal antibody that neutralizes SA alpha toxin. SAATELLITE, a phase 2 study of safety and efficacy of suvratoxumab for reducing the incidence of SA pneumonia (NCT02296320) was conducted and recently completed within the consortium for Combating Bacterial Resistance in Europe. We investigated the performance of a

rapid PCR test (Xpert MRSA/SA SST1[®], Cepheid) as a screening tool during the study and the association between SA load and suvratoxumab efficacy.

Methods. The PCR assay was used to detect SA and methicillin-resistant SA (MRSA) in lower respiratory tract (LRT) samples. Culture was performed on PCR SA+ LRT samples according to local procedures. PCR SA+ subjects were randomized 1:1 to either a single intravenous infusion of 5000 mg suvratoxumab (*n* = 96) or placebo (*n* = 100) and followed for 190 days post dose. Efficacy of suvratoxumab was defined as relative risk reduction (RRR) in incidence of SA pneumonia within 30 days post-dose compared with placebo.

Results. 299 (41.5%) out of 720 screened subjects were SA+ by PCR. Of 209 subjects with culture data, there were 162 (77.5%) SA+, 47 (22.5%) SA- and 9 (5.6%) MRSA by culture. Culture results could have been affected by antibiotic use and site variability in limits of detection ranging from 3.3 to 100,000 colony-forming units per mL (CFU/mL). No discordance was noted between PCR and culture for MRSA detection. An inverse linear correlation was observed between the PCR cycle threshold (Ct) values for SA protein A gene (*spa*) and SA CFU/mL counts from quantitative culture. In subjects with low SA load (Ct ≥ 29; *n* = 72), suvratoxumab provided 66.7% RRR [90% confidence interval (CI): 21.3%, 86.2%] compared with 31.9% RRR [90% CI: -7.5%, 56.8%] in total study population.

Conclusion. Cepheid Xpert PCR assay was easy to perform, sensitive and standardized, and provided better sensitivity than conventional culture for detection of SA. Additionally, quantitative PCR Ct output was associated with the efficacy of suvratoxumab in reducing SA pneumonia incidence.

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2161. Organism-Specific Turn Around Time Improvement in Urinary Specimens as a Result of Microbiological Laboratory Automation

Nouman Farooq, MD¹; Alanna Emrick, MLS(ASCP)cm, SMCm²; Carolyn Gonzalez-Ortiz, M(ASCP)cm²; David Sellers, RN³; Ying P. Tabak, PhD³; Latha Vankeepuram, MS³; Stephen Kurtz, MS³; Fatma Levent, MD¹; Texas Tech University Health Sciences Center, Lubbock, Texas; UMC Health System, Lubbock, Texas; BD, Vestavia, Alabama

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Background. University Medical Center in Lubbock, TX is one of few medical centers using Becton Dickinson (BD) Kiestra Total Laboratory Automation (TLA) system since May 2015. The impact on organism-specific turn around time (TAT) in urinary specimens after implementation of TLA was evaluated.

Methods. After approval from the Quality Improvement Review Board, a retrospective analysis of microbiological data from urinary specimens in BD research database was performed. Before vs. after implementation (2013 vs. 2016) TAT was compared. Ten clinically relevant organisms were analyzed. Statistical analysis was performed with SAS software version 9.2. Data were analyzed using *Chi-squared test*. A *P*-value of < 0.05 was considered statistically significant.

Results. Overall, 2282 specimens from 2013 and 2306 specimens from 2016 were analyzed. Compared with before vs. after implementation of TLA, an overall improvement in TAT was observed (expressed as mean hours for each organism): *Enterococcus faecalis* (55.2 vs. 38.8), *Enterococcus faecium* (68.4 vs. 43.8), *Escherichia coli* (44.2 vs. 41.0), *Klebsiella pneumoniae* (45.0 vs. 44.0), *Proteus mirabilis* (44.8 vs. 38.6), *Pseudomonas aeruginosa* (58.9 vs. 37.7), *Staphylococcus aureus* (49.2 vs. 36.0), *Streptococcus agalactiae* (49.2 vs. 31.4), *Streptococcus pneumoniae* (51.7 vs. 61.8), *Streptococcus pyogenes* (62.6 vs. 26.6). It was also observed that improvement in TAT was more pronounced for Gram-positive organisms than Gram-negative organisms. *P*-value was < 0.01 for all organisms except *Streptococcus pneumoniae* (0.7985) and *Streptococcus pyogenes* (0.2562). The number of specimens with these two organisms was too small to be considered significant.

Conclusion. Automation of microbiology laboratory leads to significant TAT improvement in urinary specimens, making early data availability to clinicians. This improves efficiency as well as supporting earlier antibiotic switch, antimicrobial stewardship and optimal patient care in treating urinary tract infections.

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2162. Comparison of Plazomicin Disk Diffusion vs. Gradient Diffusion Susceptibility Testing Results Against Drug-Resistant Clinical *Enterobacteriaceae* Isolates

Alexander Lepak, MD¹; Alexander Lepak, MD¹; Luriane Grajevci, BS²; Joyce Banach, MT(ASCP)³; Katherine Meyer, BS²; Derrick Chen, MD¹; University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin; University of Wisconsin Health, Madison, Wisconsin

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Background. Plazomicin, a novel aminoglycoside, is active against carbapenem-resistant *Enterobacteriaceae* (EB) and is not inhibited by most aminoglycoside modifying enzymes that affect gentamicin and tobramycin. We investigated the activity of plazomicin against resistant EB clinical isolates and compared disk diffusion (DD) vs. gradient diffusion (GD) results.

Methods. EB isolates that were carbapenem resistant and/or resistant to both gentamicin and tobramycin were retrieved from the UW Health clinical isolate repository. Each isolate was tested against plazomicin using both DD (MAST Group Ltd. Plazomicin disk 30 µg) and GD (Liofilchem Plazomicin MIC Test Strip 0.16–256 µg/