the cephalosporin and aztreonam groups, respectively (3% vs. 11%, p=0.082, 20% vs. 12%, p=0.451). Because cephalexin has a similar R1 side chain to aminopenicillins, five patients with an aminopenicillin allergy who received cephalexin were evaluated separately; none had an allergic reaction (Table 1, Table 2, Figure 2).

## Table 1: Baseline Characteristics

	Aztreonam (n = 81)	Cefazolin/Cephalexin (n = 139)
Age at admission, years*	60 (46 - 77)	49 (33 - 66)
Sex, female	49 (60%)	99 (71%)
Race		
Asian	2 (3%)	0 (0%)
African American	5 (6%)	15 (10%)
Caucasian	61 (75%)	104 (75%)
East Indian	0 (0%)	1 (1%)
Other	13 (16%)	18 (13%)
Unknown	0 (0%)	1 (1%)
Pregnant*	1 (1%)	23 (17%)
Reported allergen**		
Natural Penicillin	76 (94%)	125 (90%)
Aminopenicillin	7 (9%)	14 (10%)
Piperacillin/tazobactam	2 (2%)	1 (1%)
Total number of drug allergies*	3 (1 - 4)	2 (1 - 3)
Antibiotic indication, most prevalent		
Cellulitis	5 (6%)	22 (16%)
Pneumonia	15 (19%)	0 (0%)
Prophylaxis	0 (0%)	13 (9%)
Surgical prophylaxis	0 (0%)	47 (34%)
Sepsis	15 (19%)	0 (0%)
UTI	15 (19%)	23 (17%)
Number of doses received*		
1 Dose	20 (25%)	74 (53%)
> 1 Dose	61 (75%)	65 (47%)
Sulfa allergy*	20 (25%)	17 (12%)
HIV infection	0 (0%)	2 (1%)
Herpes viral infection	1 (1%)	3 (2%)

Data represented as n (%) or median (interquartile range) \*P value < 0.05

\*\*Some patients had anaphylaxis allergies to more than one penicillin

The median age was higher in the aztreonam group, and the majority of patients were female and Caucasian. There were significantly more pregnant females in the cephalosporin group, and the majority of patients reported a natural penicillin allergy.

### Table 2: Outcomes

Primary Outcome				
	Aztreonam (n = 81)	Cefazolin/Cephalexin (n = 139)	p value	
Allergic reactions	11 (14%)	9 (7%)	0.077	
	Secondary Outcome	25		
	Aztreonam (n = 81)	Cefazolin/Cephalexin (n = 139)	p value	
IgE-mediated reactions	11 (14%)	8 (6%)	0.046	
Antibiotic discontinued	0 (0%)	0 (0%)		
30-day readmission for delayed hypersensitivity reaction	0 (0%)	0 (0%)		
	< 2 Drug Allergies (n = 83)	$\geq 2$ Drug Allergies (n = 137)	p Value	
Allergic reactions	8 (10%)	12 (9%)	0.826	
	1 Dose Aztreonam (n = 20)	> 1 Dose Aztreonam (n = 61)	p Value	
Allergic reactions	4 (20%)	7 (12%)	0.451	
	1 Dose Cephalosporin (n = 74)	> 1 Dose Cephalosporin (n = 65)	p Value	
Allergic reactions	2 (3%)	7 (11%)	0.082	
	Patients who Received Cephalexin with Aminopenicillin Allergy (n = 5)			
Allergic reactions	0 (0%)			

Data are n (%); P value: <0.05 is statistically significant

There were less allergic reactions (IgE or non-IgE mediated) in the first-generation cephalosporin group compared to the aztreonam group, but this was not statistically significant. Also, there were fewer IgE-mediated reactions in the cephalosporin group. There was no difference in allergic reactions in patients with two or more reported drug allergies compared to less than two drug allergies. No difference in allergic reactions was observed when comparing those who received a single antibiotic dose versus multiple doses within the cephalosporin and aztreonam groups. Of the five patients who received cephalexin and reported an aminopenicillin anaphylactic allergy, none had an allergic reaction. Additionally, there were not any patients readmitted within 30 days for delayed hypersensitivity reactions and no antibiotics were discontinued due to other documented adverse reactions.

### Figure 2: Occurrence of Allergic Reactions



Of the patients who had allergic reactions in the cephalosporin and aztreonam groups, these included immediate airway compromise, hypotension with one patient in the aztreonam group receiving vasopressors within the pre-defined time frame, receipt of the non-standing rescue medication of diphenhydramine, and drug rash.

**Conclusion.** There was no difference in the incidence of allergic reactions between the aztreonam and first-generation cephalosporin group, and fewer serious allergic reactions occurred in the cephalosporin group. This study suggests that cefazolin and cephalexin can safely be used in patients who report anaphylaxis to an agent in the penicillin class.

Disclosures. Janessa Smith, PharmD, Merck & Co. (Employee)

# 144. Clinical Validation and Performance of a T-cell Immunosequencing Assay to Identify Past SARS-CoV-2 Infection

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### Session: O-30. Research in COVID-19 Diagnostics

**Background.** Our understanding of the SARS-CoV-2 immune response has critical gaps that are inadequately addressed with available tools. We report the clinical performance of T-Detect COVID, the first T-cell assay to identify prior SARS-CoV-2 infection using T-cell receptor (TCR) sequencing and repertoire profiling from whole blood samples.

*Methods.* The T-Detect COVID assay combines high-throughput immunosequencing of the TCRß gene from blood samples with a statistical classifier demonstrating 99.8% specificity for identifying prior SARS-CoV-2 infection. The assay was employed in several retrospective and prospective cohorts to assess primary and secondary Positive Percent Agreement (PPA) with SARS-CoV-2 RT-PCR (N=205; N=77); primary and secondary Negative Percent Agreement (NPA; N=87; N=79); PPA compared to SARS-CoV-2 serology (N=55); and pathogen cross-reactivity (N=38). The real-world performance of the test was also evaluated in a retrospective review of test ordering (N=69) at a single primary care clinic in Park City, Utah.

**Results.** In validation studies, T-Detect COVID demonstrated high PPA (97.1%  $\geq$ 15 days from diagnosis) in subjects with prior PCR-confirmed SARS-CoV-2 infection; high NPA (~100%) in SARS-CoV-2 negative cases; equivalent or higher PPA with RT-PCR compared to two commercial EUA antibody tests; and no evidence of pathogen cross-reactivity. Review of assay use in a single clinic showed 100% PPA with RT-PCR in individuals with past confirmed SARS-CoV-2 vs. 85.7% for antibody testing, 100% agreement with positive antibody results, and positive results in 2/4 convalescent subjects with seroreversion to a negative antibody. In addition, 12/69 (17.3%) individuals with absent or negative RT-PCR tested positive by T-Detect COVID, nearly all of whom had compatible symptoms and/or exposure. TCR positivity was observed up to 12+ months (median 118 days) from the date of positive RT-PCR.

**Conclusion.** A T-cell immunosequencing assay shows high clinical performance for identifying past SARS-CoV-2 infection from whole blood samples. This assay can provide additional insights on the SARS-CoV-2 immune response, with practical implications for clinical management, risk stratification, surveillance, assessing vaccine immunity, and understanding long-term sequelae.

Disclosures. Sudeb C. Dalai, MD, PhD, Adaptive Biotechnologies (Employee, Shareholder) Jennifer N. Dines, MD, Adaptive Biotechnologies (Employee, Shareholder) Thomas M. Snyder, PhD, Adaptive Biotechnologies (Employee, Shareholder) Rachel M. Gittelman, PhD, Adaptive Biotechnologies (Employee, Shareholder) Tera Eerkes, PhD, Adaptive Biotechnologies (Employee, Shareholder) Pashmi Vaney, PhD, Adaptive Biotechnologies (Employee, Shareholder) Sally Howard, PhD, Adaptive Biotechnologies (Employee, Shareholder) Kipp Akers, PhD, Adaptive Biotechnologies (Employee, Shareholder) Lynell Skewis, PhD, Adaptive Biotechnologies (Employee, Shareholder) Anthony Monteforte, PhD, Adaptive Biotechnologies (Employee, Shareholder) Pamela R. Witte, PhD, Adaptive Biotechnologies (Employee, Shareholder) Cristina Wolf, PhD, Adaptive Biotechnologies (Employee, Shareholder) Hans Nesse, PhD, Adaptive Biotechnologies (Employee, Shareholder) Jia Qadeer, PhD, Adaptive Biotechnologies (Employee, Shareholder) Sarah Duffy, PhD, Adaptive Biotechnologies (Employee, Shareholder) Emily Svejnoha, PhD, Adaptive Biotechnologies (Employee, Shareholder) Caroline Taromino, PhD, Adaptive Biotechnologies (Employee, Shareholder) Ian M. Kaplan, PhD, Adaptive Biotechnologies (Employee, Shareholder) John Alsobrook, MD, Adaptive Biotechnologies (Employee, Shareholder) Thomas Manley, MD, Adaptive Biotechnologies (Employee, Shareholder) Lance Baldo, MD, Adaptive Biotechnologies (Employee, Shareholder, Leadership Interest)

# 145. SARS-CoV-2 (COVID-19) Testing Experience within a Military Treatment Facility

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