Introduction/Objective: Targeted therapies have been successfully used for the treatment of lung adenocarcinoma but have not been implemented in the treatment of lung squamous cell carcinoma (SqCC). In order to better understand the underlying biology of SqCC, we present comprehensive Next Generation Sequencing (NGS) data via Cancerplex from SqCC. We have observed frequent mutations in p53, CDKN2A, PTEN, CDKN2B, and TGFBR2 genes together with few new rare gene mutations.
Methods: Twenty-one patients with diagnosis of Lung SqCC have been selected for Cancerplex assay (Kew, Inc., Waltham, MA). Formalin-fixed tissues from these patients were used for the assay. Neoplastic tissues with tumor content higher than 20% were micro-dissected from the blocks and NGS was performed with at least 50 ng DNA content and with a limit of detection of 10% mutant alleles. The depth of coverage was 500, and the size of the targeted region was 2.8 Mb. Results were compared with published databases.
Results: We have observed p53 mutations in 100% cases. p53 gene mutations included single point mutations with various coding protein mutations as well as splice variants. Mutations in CDKN2A is found in 47.6% of cases; PTEN mutations in 33.3% of cases; CDKN2B mutations in 28.6% of cases, and TGFBR2 in 28.6% of cases, which has been reported as actionable variants and actionable copy number variants.
Conclusion: Previous literatures have provided evidence that SqCC arising in different anatomical sites share common genomic mutation patterns. Our data partially supports this finding. We demonstrated p53, CDKN2A and PTEN are among the most commonly mutated genes in lung SqCC, while a few other genes mutations does not fit in this pattern. Apparently more studies need to be done to provide a more clear genetic landscape of SqCC, which would facilitate the development of targeted therapies.

Novel Autoantibodies Biomarkers Panel to Prognosticate the Clinical Outcomes in Advanced-stage NSCLC Patients Receiving Anti PD-1/PD-L1 Immunotherapy

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Introduction/Objective: Lung cancer is the leading cause of cancer-related deaths worldwide, with a majority of cases detected at a non-resectable advanced stage. Current anti PD-1/-L1 therapy has reformed cancer treatment strategies with remarkable clinical outcomes in non-small cell lung cancer (NSCLC). However, the overall response rate is still marginal, demonstrating the need for biomarkers predictive of response. The objective of this study is to develop a serum based panel to prognosticate clinical response in advanced NSCLC patients receiving anti PD-1/-L1 therapy.
Methods: Pooled sera from two response groups (Poor response, n=20, overall survival < 12 months; Good response, n=20, overall survival > 12 months) were evaluated via the HuProt™ Human Proteome Microarray (CDI laboratories, Baltimore, MD) to identify expressed neoantigens. Recombinant proteins representative to identified neoantigens along with their corresponding antibodies, were commercially acquired to develop a robust 13-plex bead- based immunoassay to evaluate the autoantibodies in pretreatment sera from 125 advanced-stage NSCLC patients. Finally, levels of autoantibodies were correlated to clinical outcome, including progression free survival (PFS), overall survival (OS) and grade III adverse events.
Results: Low baseline levels of ZNF695, MCM4, PRMT2, FGD3, GTF2A1, GLUL, CDCA3, ZNF277, GARS, GBP2, UBL7, and ASNA1 autoantibodies were found to be associated with a longer PFS (all p-values < 0.01), whereas increased levels were associated with a poor PFS outcome (0.06, HR=0.66, 95% CI). Low levels of ZNF695, MCM4, PRMT2, FGD3, GARS, GBP2, and UBL7 autoantibodies were associated with favorable OS (all p-values < 0.01).
Conclusion: In this study we demonstrated that serum autoantibodies have great promise to serve as a prognostic tool for immunotherapy response. We successfully developed a high performance multiplexed serum based assay to evaluate autoantibodies in an advanced NSCLC patients receiving anti PD-1/-L1 therapy.

The Wild West of Emergency Use Authorizations for SARS-CoV-2 Testing: What Could Be the True Sensitivity?

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Introduction/Objective: SARS-CoV-2 is a pandemic that has required mobilization to meet urgent needs. In this mobilization, emergency use authorizations (EUA) have been issued by the FDA to expedite the deployment of these tests. This has led to a situation whereby sensitivity has not been rigorously studied for any of the assays with EUAs. Estimates can be extrapolated from the limited samples documented by the company in their instructions for use (IFU). Although the nationwide shortage of testing reagents prevent parallel testing of multiple platforms on all specimens, observations of repeat specimens at the Veteran Affairs Medical Center (VAMC) provides

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the first study in the literature of more complete data for SARS-CoV-2 nucleic acid (RT-PCR) assay on sensitivity on the Abbott (Abbott Park Ill) and Cepheid (Sunnyvale CA) assays.

Methods: A retrospective search was performed for all test results for SARS-CoV-2 by RT-PCR from 3/1/2020 to 4/14/2020 at Corporal Michael J. Crescenz Medical Center, in order to evaluate the sensitivity on Abbott m2000 and Cepheid platforms. Results across multiple reference laboratories and in-house testing platforms were collated in a table with all patients clinically requiring repeat testing recorded.

Results: 114/863 patients had repeat testing. The tests were performed initially by outside reference laboratories (25 patients), on the Abbott m2000 (63 patients), and Cepheid Infinity (26 patients). 15/114 (13%) had discordant results on repeat testing. This included 1 test initially done by a reference laboratory. 8 days after the initial result from the reference lab, a positive for the same patient was identified on the Abbott platform. 11 initial Abbott results were discordant on further repeat testing on two platforms - Abbott (6 patients) and Cepheid (5 patients) 1-6 days later. In addition, 3 initial Cepheid were discordant on further repeat testing by the same Cepheid platform (1-16 days later).

Conclusion: While the instructions for use for both platforms suggest 100% sensitivity and specificity (due to the 100% positive and negative percent agreement in limited specimens), the true sensitivity is less than 100%, particularly early in the course of the infection. In our study, the positive percent agreement (surrogate for sensitivity) was 83% for initial Abbott tests, 88% for initial Cepheid tests, and 95% by Reference laboratory platform.

Assessment of Matrix-Assisted Laser Desorption/ Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF- MS) for Accurate Bacterial Identification in Clinical Labs

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Introduction/Objective: On behalf of the diagnostic Medical Laboratory rapid, and accurate identification of bacteria with their one-to-one anti-microbial susceptibility outlines is of ultimate importance for the management of infected patients. Contemporary microbial identification methods employed in routine clinical diagnostic laboratories relies on the use of conventional phenotypic methods. Phenotypic methods are time consuming with minimum turn-around times of at least 24 hrs and in many occurrences of 48hrs. With the intention of accelerate laboratory processes the MALDI-TOF MS was familiarized. MALDI-TOF MS is established on proteomic profiling and permits for rapid identification of bacteria. This technology has not been widely used in Egypt, but has been regularly used in Europe for the past few years.

Methods: Two hundred forty three positive non duplicate blood cultures were accrued over a period of six months. Experimental aliquots were taken from excess sample material that was collected as part of routine clinical care. 105 were positive for Gram negative bacilli, 123 were positive for Gram positive cocci, 3 positive for Gram positive bacilli, and 7 were positive for yeast. MALDI-TOF identification was compared to conventional identification. Conventional identification consisted of a combination of MALDI-TOF identification of a subcultures colony by direct smear, biochemical reactions, Vitek 2, and molecular identification.

Results: Ninety seven of the one hundred and five blood cultures positive for Gram negative bacilli were monomicrobial. The majority of these were identified as Escherichia coli by conventional methods, followed by Klebsiella pneumoniae and Pseudomonas aeruginosa. Eighty-four of these monomicrobial cultures were identified by MALDI-TOF to the species level. Eighty-one of the eighty-four were concordant with the conventional identification (96.4%).

Conclusion: The MALDI-TOF proved to be useful for the rapid and reliable identification of g-ve bacteria from the clinical specimens. The difference in turnaround time for bacterial identification was significant between MALDI-TOF MS and VITEK 2 with minimal preparation for the blood cultures.

Ethnic Differences in Infection with SARS-CoV-2; a Veteran Affairs Medical Center (VAMC) Experience

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Introduction/Objective: An Institute of Medicine (IOM) report from 2002 has documented that racial and ethnic minorities have tended to receive worse health outcomes compared to non-minorities. This pattern has been demonstrated for many chronic and acute injuries and illnesses, but to the author's knowledge, there is sparse literature on this study on outcomes related to the novel coronavirus (SARS-CoV-2). SARS-CoV-2 has become a pandemic of global importance with significant impact on all elements of society. As part of quality assurance, as becoming confirmed positive for

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