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**Purpose:** Despite the rollout of several vaccines targeting SARS-CoV-2, attainment of near-universal vaccination is a challenging task, particularly for low- and middle-income nations such as Sri Lanka. Rapid, reliable diagnostics for the detection of the virus is of vital importance for the predominantly export- and tourism-based economy of the country. Herein, we report the development of a RT-LAMP assay as an alternative to the gold-standard RT-qPCR method for diagnostic laboratories in Sri Lanka in a cost-effective and highly reliable manner.

**Methods & Materials:** About 313 nasopharyngeal and oropharyngeal samples from the community were collected and subjected to RNA purification and subjected to simultaneous RT-qPCR and RT-LAMP experiments by using previously published primers in a thermocycler. Duplex (containing N and E gene primers) and multiplex (containing N, E and ORF1ab gene primers) RT-LAMP assay results were compared with standard RT-qPCR results using an agreement attribute statistical test. The effect of guanidine hydrochloride was also analyzed.

**Results:** The limit of detection for the duplex assay was found to be 10 copies  $\mu$ L<sup>-1</sup> at a constant temperature of 63°C, and 5 copies  $\mu$ L<sup>-1</sup> for multiplex assays at 66.4°C. Both types of RT-LAMP assay were specific only for the SARS-CoV-2 virus, successfully distinguishing it from multiple other human viruses. Attribute agreement analysis between duplex- and multiplex RT-LAMP vs RT-qPCR yielded 93% and 96.5% scores, respectively. Moreover, both RT-LAMP assays showed 100% agreement with RT-qPCR when Ct was <25 in positive samples and showed 100% (duplex) or 97.22% (multiplex) at 35  $\geq$  Ct  $\geq$  25. The discrepancy between agreements at higher Ct values was attributed to the higher sensitivity of the multiplex RT-LAMP assay. The addition of guanidine hydrochloride increased the sensitivity and decreased detection time significantly for both the duplex and multiplex assays.

**Conclusion:** Overall, we have demonstrated a potentially rapidly deployable diagnostic test kit not only for widespread community use but particularly for high-risk locations such as ports of entry or manufacturing facilities to mitigate the effects of the SARS-CoV-2 virus in Sri Lanka.

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**PS05.04 (947)**

**Treatment with Ivermectin Is Associated with Decreased Mortality in COVID-19 Patients: Analysis of a National Federated Database**

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**Purpose:** To evaluate the difference in mortality of patients treated with ivermectin vs patients treated with remdesivir with

COVID-19 in United States using TriNetX Research network, a federated EMR network of over 44 healthcare organizations and 68 million patients from US, from 2009–2021.

**Methods & Materials:** We retrospectively identified adults ( $\geq$ 18 years) with a recorded COVID-19 infection between January 1, 2020 and July 11, 2021. We compared those with recorded use of ivermectin, but not remdesivir, against those with recorded use of remdesivir, but not ivermectin. We controlled for the following demographics, comorbidities, and treatments that may affect COVID-19 survival outcomes: age, gender, race, ethnicity, nicotine use, diabetes mellitus, obesity, chronic lower respiratory disease, ischemic heart diseases, tocilizumab, glucocorticoids, or ventilator use. We measured association with mortality as the primary outcome, with significance assessed at  $p < 0.05$ .

**Results:** There were a total of 1,761,060 possible COVID-19 patients based on ICD-10 diagnostic terms and confirmatory lab results. Prior to controlling, our analysis yielded 41,608 patients who had COVID-19 resulting in two unique cohorts that were treated with either ivermectin (1,072) or remdesivir (40,536). Within the ivermectin cohort, average age was 51.9 + 17.8 years, 43% were male, 60% had glucocorticoids and 1% required ventilator support. In the remdesivir cohort, average age was 62.0 + 16.0 years, 54% were male, 64% had glucocorticoids and 2% required ventilator support. After using propensity score matching and adjusting for potential confounders, ivermectin was associated with reduced mortality vs remdesivir (OR 0.308, 95% CI (0.198,0.479)), Risk Difference -5.224%, CI (-7.079%,-3.369%),  $p < 0.0001$ .

**Conclusion:** Ivermectin use was associated with decreased mortality in patients with COVID-19 compared to remdesivir. To our knowledge, this is the largest association study of patients with COVID-19, mortality and ivermectin. Further double-blinded placebo-controlled RCTs with large samples are required for definite conclusion. In the future, if more publications are published with the similar result to the current analyses, the certainty of evidence will increase.

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**PS05.05 (359)**

**Surveillance of Immunological Status after Vaccination by two Serological Assays based on SARS-CoV-2 Spike Protein**

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**Purpose:** Two serological assays, an Enzyme-Linked Immunosorbent Assay (ELISA) and a Lateral Flow Assay (LFA), have been developed based on the SARS-CoV-2 recombinant Receptor Binding Domain (RBD-ELISA) and the combination of Trimeric Spike (S) and Nucleoprotein (N), S-LFA and N-LFA, respectively, as

candidate tools for both indirect measurement of virus circulation and assessment of infection and vaccine-induced immunity.

**Methods & Materials:** A total of 1272 human serum samples collected from volunteers (SARS-CoV-2 infected, non-infected or vaccinated) were evaluated by the two assays. For the RBD-ELISA, plates were coated with RBD, sera were added at 1/5 dilution and bound antibodies were detected with RBD labelled with Horseradish Peroxidase. For the LFA, two parallel strips were used: one for detection of N-specific antibodies (Hoste A. et al, 2020); and another one for detection of S-specific antibodies, using S both as capture and detector reagent. Twenty microliters of blood or ten microliters of serum were applied to each cassette and results were interpreted after ten minutes.

A seroneutralization assay was used as reference for the detection of neutralizing antibodies with RBD-ELISA and Reference sera (World Health Organization), for determination of the Limit of detection (LoD). MedCalc® 10 software was used for statistical analysis.

**Results:** The potential diagnostic application with sera from naturally infected and non-infected volunteers showed sensitivity, specificity and agreement (kappa) values of 95.1%, 99.0% and 0.94 respectively for RBD-ELISA; while 97.2%, 99.3% and 0.967 respectively for N-LFA; or 93.2% 98.3 %, 0.923, respectively for S-LFA. Serum samples from vaccinated individuals were analyzed for the specific detection of antibodies to the S protein: for vaccinated but non-infected individuals, sensitivity reached 97.3% after 15 days post-second vaccination dose whereas for previously infected people reached 100% after only 15 days post-first dose. The performance of RBD-ELISA showed good agreement with seroneutralization and excellent agreement with S-LFA (kappa 0.979).

**Conclusion:** The dual N/S LFA represents a valuable tool to detect SARS-CoV-2 infection due to its complementary information on N and S-specific antibody response. Furthermore, the S-LFA and RBD-ELISA are both proven to be able to determine the extent of antibody response after vaccination.

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#### PS05.06 (900)

##### Comparison of Cycle Threshold and Clinical Status Among Different Age Groups of COVID-19 Cases

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**Purpose:** Aim of the study was to compare the viral load and clinical status among different age groups with COVID-19 infection

**Methods & Materials:** A retrospective cross-sectional study was carried out to analyse the Ct values of positive samples reported during April 2020 till May 2021. Result of 13,820 number of RT-PCR positive samples were included for analysis of Ct values. Ct values of confirmatory genes were taken into consideration and Ct values below 25, >25 to 30 and >30 was categorized as high, moderate and low viral load respectively. Age group was stratified into ≤18 years, 18-60 and >60 years as young, adult and elderly respectively. The data was analysed using SPSS windows version 25.0.

**Results:** The Mean Ct value was 27.9, 26, and 26.2 in young, adult and elderly age group respectively. Mean Ct value of young patients were significantly higher as compared to adult and elderly patients (p<0.05). The percentage of high viral load (Ct<25) was found to be significantly higher in adults and elderly (44.6% & 43.7%) as compared to young (32.2%) (p<0.001). Majority of the covid 19 positive cases belonging to <18 years age (75.9%) were asymptomatic as compared to 64.5% and 59.7% in adult and elderly age groups respectively.

**Conclusion:** Present study observed a significantly high proportion of viral load in the adult and elderly population which plays a substantial contribution to SARS CoV-2 transmission, whereas the majority of the young population being asymptomatic play major role as silent transmitters. The study reemphasizes the need for strict adherence to COVID appropriate behaviours.

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#### PS05.07 (121)

##### SARS-CoV2-associated multisystem inflammatory syndrome in children: data from Khimki hospital

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**Purpose:** Multisystem inflammatory syndrome in children (MIS-C) – the most severe status, associated with SARS-COV-2 infection. Clinical and laboratory characteristics of MIS-C, and treatment optimization are topical problems on current stage. Our aim to analyze main features of the MIS-C.

**Methods & Materials:** We evaluated 41 children (21M/18F) 1 - 16 yrs. (8,45±0,677 yrs.) hospitalized in Khimki Regional Hospital with MIS-C from June 2020 to April 2021. 7 children had background disease (allergy, nephroblastoma, ulcerative colitis, diabetes mellitus, urologic pathology). 5 children were mongoloid race (12%). Excessive weight had 27%, according to BMI; 17% had high growth to age. 58% had A(II) blood group, Rh(+)-positive were 74%.

**Results:** All children at the admission had fever more than 3 days. Anti-SARS-COV-2 IgM and IgG had 1 patient, IgG only - 25 (61%); 2 patients were positive SARS-Cov2 RNA in the oropharyngeal swab; 27% had family contact to COVID-19. By severity 66% children were hospitalized to the ICU. Clinically skin and mucosal signs had 31 (76 %), gastro-intestinal symptoms – 22 (54%), pneumonia – 20 (49%), kidney injury –15 (40%), cardiovascular damage - 10 (24%), CNS –6 (15%). Simultaneous damage of 2 systems had 37% children, 3 – 46%, 4 - 12%, 5 – 1 patient, 6 – 1 patient. 5 cases developed acute kidney injury like hemolytic-uremic syndrome (HUS), as the main MIS-C performance.

Laboratory features: increased ESR (Me 40,0 (IQR 30-50) мм/ч), elevated CRP (Me 118,9 (IQR 71,5-129,4)), ferritin (Me 471,0 (IQR 214,08-990,28)), D-dimer (Me 2,81 (IQR 1,76 – 4,55)), LDH (Me 594,0 (IQR 511,0-663,0)), CK (Me 112,0 (IQR 61,35-288,7)), CK-MB (Me 44,95 (IQR 33,0-80,1)), decreased albumin (Me 27,4 (IQR 23,0-33,0)). In 76% patients were treated with methylprednisolone pulse, IVIG in 20%, standard doses of corticosteroids – 10%. All children discharged home with recovery.

**Conclusion:** MIS-C is the most severe form of COVID-19 in children. In Khimki Regional Hospital 41 patient were successfully treated. The main features are severe status (66%-ICU), 63% children had 3+ affected systems; the main symptoms are skin and mucosal damage, gastrointestinal signs and headache, high BMI. There were 5 patients with HUS, during SARS-Cov2 associated MIS-C.

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