



COVID and respiratory infections

Monthly report April 2022



Executive Summary

- Mandatory PCR mass screening in Shanghai, China due to recent outbreak (26M in 36hrs, pooling allowed).
 - Massive NAC demand March - mainly through Thermo.
 - Enquiry from Personal Health (Nexar customer), Shanghai – plan on improving mass screening capabilities. LoD requirement pooled samples, on-site support level (service/ applications), NMPA approval, and local pricing expectation to address before proceeding.
- Declining volumes for molecular testing North America, EMEA, unclear demand respiratory panels currently – expected autumn/ winter.

NA Trends, Competition, VOC ,Regulatory/ govt

- COVID: Total cases 80.1M (79.2M previously wk of 09.03.2022) with daily new cases of 29.7k(48.3k previously) 7 day average, death toll 981K (957K previously). 1.79 dailytests/thousand (3.60 previously)
- Influenza wk 12: Natiional Clinical Labs, 6.5% US (total of 2994 influenza A and 23 influenza B) Canada reporting week 10: (total of 7 influenza A and 0 influenza B)
- RSV wk 12: cases confirmed via antigen testing 23; via PCR 243

Key Areas	Marketing Intelligence	Implications for LGC
Market Trends	<ul style="list-style-type: none"> • Cue Health Gets Authorization to Offer At-Home COVID-19 Test in Canada • Quest Receives \$19.5M Contract From CDC for COVID-19 Serology Testing • Visby Medical Executes \$25.5M BARDA Contract to Develop At-Home Flu, COVID-19 PCR Test 	<ul style="list-style-type: none"> • The isothermal amplification test consists of the single-use test cartridge and a wand for collecting lower nasal swab samples. It runs on the portable Cue Health Monitoring System, also authorized for sale in Canada, and displays test results on a connected mobile device in about 20 minutes via an app • Continue to monitor for opportunity as they work on the at-home assay currently in development is a single-use, handheld, all-in-one PCR device that detects and distinguishes influenza A, influenza B, and SARS-CoV-2, delivering results in less than 30 minutes
Competition	<ul style="list-style-type: none"> • Applied Ingenuity Diagnostics moving away from using our COVID oligos 	<ul style="list-style-type: none"> • IDT offered a 48 hour TAT and we said we could ship in 3 weeks
VOC Customer/ account news	<ul style="list-style-type: none"> • Ipsum Diagnostics sample volume has gone down currently like everywhere they are esting 200-250 samples /day average. • Oxy-Gen labs goal is to completely move away from COVID testing by end of year and return to BAU testing • Molecular Designs has a goal to remove COVID samples as a part of their business model • Applied Ingenuity Diagnostics looking to move towards full respiratory panel and UTI/STI testing; however, they are planning to develop a COVID test using LAMP with NIH grant money. This is moreso for platform development and would be used for different pathogens upon platform design 	<ul style="list-style-type: none"> • Anticipating 1000 nM bulk for 4-6 months (Valu Panel CDC Flu SC2) • As they are looking to move to full respiratory panel and STI panel by PCR, cancer panel by NGS – presents opportunity to continue with BAU • Instead need to transition to successful full respiratory panel (FluA/FluB/COVID/RSV) and UTI/STI testing
Regulatory/ Govts	<ul style="list-style-type: none"> • Minute Molecular Diagnostics COVID-19 Test receives FDA EUA. • Helix Obtains FDA Emergency Use Authorization for SARS-CoV-2 Molecular Test With Self-Collection. Quest Diagnostics Gets FDA Emergency Use Authorizations for DTC COVID-19 Tests, Self-Collection Kit • Baebies Receives CE Mark for Molecular POC SARS-CoV-2 Test • Innova receives CE Mark for Self-Testing for SARS-CoV-2 Antigen Test 	<ul style="list-style-type: none"> • The DASH SARS-CoV-2/S RT-PCR test, returns results in approx 15 minutes from nasal swab and runs on the DASH Analyzer, which consolidates the sample extraction, amplification, and thermocycling processes. The POC platform is portable and can be operated by untrained users • The test is authorized for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are self-collected without supervision using the Helix COVID-19 Self-Collection Kit by individuals 18 or older who are suspected of having COVID-19 by a healthcare provider. Testing is limited to Helix's CLIA-certified laboratories in San Diego.

LATAM Trends, Competition, VOC, Regulatory/ govt

- Covid-19 numbers in the region: 67.53M reported infections (64.28M on Feb 23rd), and 1.675M (1.64M on Feb. 23) reported deaths in the region so far. Covid-19 activity is overall low in the region.
- Influenza activity also low, although some parts are detecting an increasing in positivity (i.e. Argentina) .
- There has been observing an increase in RSV activity in Brazil, Argentina, Uruguay and Paraguay.
- Demand of tests has decreased sharply due to reduced numbers of infections.

Key Areas	Marketing Intelligence	Implications for LGC
Market Trends	<ul style="list-style-type: none"> • Reduced demand on tests in the region. • Increase analysis of respiratory virus through multiplex qPCR - Influenza A, B, RSV, Sars-Cov-2 and RNaseP as control (5-plex). • Customers migrating to other application than Covid-19: HPV detection a trend in all region. 	<ul style="list-style-type: none"> • Reduced demand for our chemistries, both extraction and PCR reagents. • Urgent opp. for development of new assays for customers, especially those using IQ and oKtopure for the Sars-Cov-2 – sales in the region last FY was 90% Covid-related.
Competition	<ul style="list-style-type: none"> • Seegene getting even stronger in the region: many panels for detection of multiples pathogens, respiratory and HPV. • Seegene won a public bid of 4M reactions last month for the Ministry of Health with their 5-plex qPCR for detection of Influenza A, B, RSV, Sars-Cov-2 and RNaseP plus crude extraction and positive and negative controls. • TMO continuous to reduce their prices in the region. • Price per portable/rental instruments – Roche and TMO 	<ul style="list-style-type: none"> • LGC could not participate in the Bid for not having the 5-plex panel ready and validated. • Aggressive competition in whole PCR detection workflow, including extraction. • Losing opportunities for not having a rental model for instruments in the region.
VOC Customer/ account news	<ul style="list-style-type: none"> • LACEN- Pernambuco: Last part of the contract was ordered - 150K reactions. Negotiations are in place for the next period. • Genes2Life – starting a molecular diagnostics lab with oktopure and intelliqube- aiming HPV and respiratory panel kits developed by them. 	<ul style="list-style-type: none"> • Opportunity for a new contract with the State Laboratory of Pernambuco. • Opportunity for consumables and oligos.
Regulatory/ Govts	<ul style="list-style-type: none"> • Most of the countries lifted the mandatory use of masks, exceptions for hospitals, health centres and public transportation. 	

APAC Trends, Competition, VOC, Regulatory/ govt

- Mandatory mass screening by PCR ongoing in Shanghai China due to the recent Omicron outbreak (26M population testing to be done in 36hrs, pooling allowed). Massive NAC demand in March - mainly through Thermo. Enquiry from existing Nexar customer in Shanghai – Personal Health that is planning on improving its future mass screening capabilities in view of the recent surge in demand. LoD requirement for pooled samples, support level required on-site (both service and applications), NMPA approval as well as cut throat local pricing expectation are critical factors to address before proceeding to further discussion.

Key Areas	Marketing Intelligence	Implications for LGC
Market Trends	<ul style="list-style-type: none"> • Most APAC countries see Omicron wave in sharp decline except Korea (just peaked, still at 266K/day), Australia (56K/day), Thailand (21K/day) as well as mainland China who is experiencing multi-city outbreaks (13K/day) – some are in extended lockdown (e.g. Jilin province and Shanghai). 	<ul style="list-style-type: none"> • Massive NAC demand out of China (mainly through TMO) and PCR components, particularly sbeadex raw beads to Genolution in Korea.
Regulatory/ Govts	<ul style="list-style-type: none"> • Mandatory mass screening by PCR ongoing in Shanghai China (26M population testing to be done in 36hrs, pooling allowed). Gov finally approved at home use of rapid antigen testing in the latest multi-city outbreak of Omicron wave. • Singapore fully opened its borders to fully vaccinated travellers (quarantine free) – on arrival test removed and pre-departure (antigen test accepted) only needed for air and sea travel. 	
VOC Customer/ account news	<ul style="list-style-type: none"> • Enquiry from existing Nexar customer in Shanghai – Personal Health that is planning on improving its future mass screening capabilities in view of the recent surge in demand. 	<ul style="list-style-type: none"> • Commercial team following up on the enquiry with input from uHTP team – LoD requirement for pooled samples (5-20 samples in a tube), support level required on-site (both service and applications), NMPA approval as well as cut throat local pricing expectation (\$2-3/sample including extraction and PCR) are critical factors to address before proceeding to further discussion.
Competition	<ul style="list-style-type: none"> • NEB promoting its virtual resource hub for MDx assay development – including LAMP and its newly launched lyophilized 1-step mix (samples offered FOC in certain territory). 	<ul style="list-style-type: none"> • Direct competition to our enzyme/mix offering – support needed to further streamline our APAC sampling program to remain agile and effective.

EMEA Trends, Competition, VOC, Regulatory/ govt

- Most of Europe prefers CE IVD labelled tests limiting B to C potential.
- Wide variation in testing numbers, most of Europe now moving towards living with Omicron.
- Combination of govt and private labs: most opp. for LGC, B to B, Many countries follow decentralized testing models, drives to reduce costs.
- B to B customers struggling to predict testing trends for respiratory viruses. Shows in difficulty accurately forecasting business.

Key Areas	Marketing Intelligence	Implications for LGC
Market Trends	<ul style="list-style-type: none"> • Most of Europe moving towards living with Omicron, with restrictions easing/ being removed. • Global key accounts have fed back that they expect multiplex respiratory panels to be in demand H2 2023 	<ul style="list-style-type: none"> • Demand for testing slowed down, seeing more non-covid / respiratory projects starting to move forward. • Incorporated into key accounts FC, but some risk
Competition	<ul style="list-style-type: none"> • Seeing ~\$0.30 per reaction as the expected price point for enzymes in Africa & Middle East. Latest info from New Bio Lab in Egypt who have this pricing from NEB 	<ul style="list-style-type: none"> • Distributor countries seeing extremely aggressive enzyme pricing – may need different strategies for different countries to win business.
VOC Customer/ account news	<ul style="list-style-type: none"> • Tail off/ stop in Covid orders from key accounts. Eg: Perkin Elmer is looking to off hand some of their Covid oligos as they are overstocked - asked if we knew of a second hand market for them! • Germany testing is still going on and customers are active but not as before 	<ul style="list-style-type: none"> • FC for COVID Q1 scaled back 800k Key Accounts EMEA • some inquiries for sbeadex but limited opps
Regulatory/ Govts	<ul style="list-style-type: none"> • Denmark is testing with respiratory panels when patients are admitted to hospital with Flu symptoms. Not 100% sure which provider, but probably largely Roche. 	<ul style="list-style-type: none"> • Not currently impacting our business.

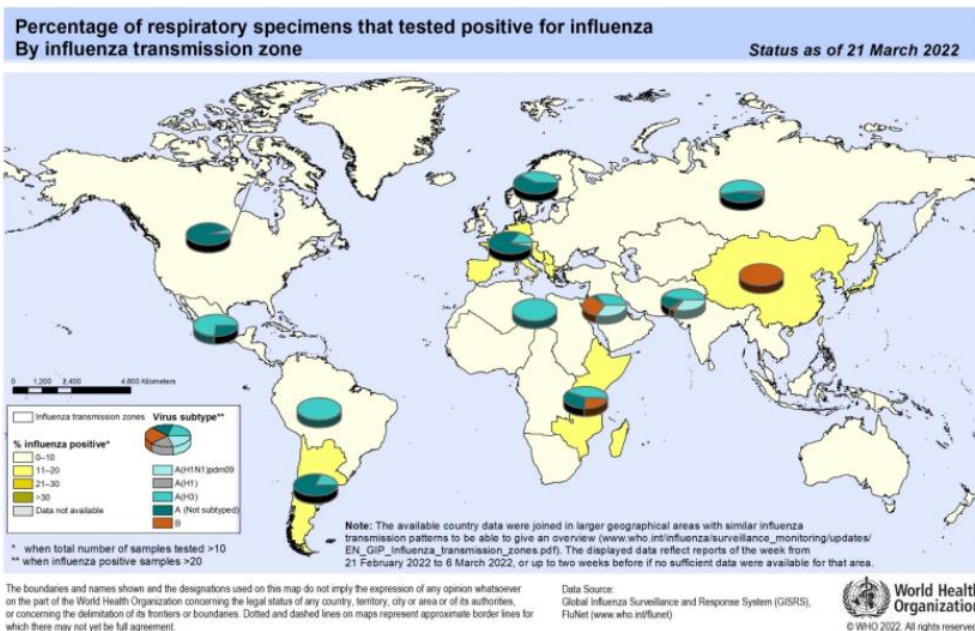
World

weekly confirmed COVID-19 Cases

Source: our world in data



Influenza situation



Globally, influenza activity remained low and decreased after a peak at the end of 2021.

- In the northern hemisphere, activity increased or remained stable with detections of mainly A(H3N2) and B/Victoria lineage v reported.
- In North America, activity increased in recent weeks but remained lower than pre-COVID-19 levels and was predominantly A, with A(H3N2) predominant among the subtyped viruses. Respiratory syncytial virus (RSV) activity further decreased.
- In Europe activity appeared to increase again with A(H3N2) predominant. Very little RSV activity was observed.
- In East Asia, activity with mainly B/Victoria lineage increased in China. Elsewhere, influenza illness indicators and activity remained low. Increased RSV activity reported in Mongolia /Republic of Korea.
- In Northern Africa, detections of influenza A(H3N2) reported.
- In Western Asia, activity was low across reporting countries.
- In the Caribbean and Central America, detections predominantly influenza A(H3N2) and activity remained low.
- In South America, low activity reported with A(H3N2) predominant.
- In Africa, activity reported from Eastern Africa with A(H3N2) predominating followed by B/Victoria lineage viruses.
- In Southern Asia, influenza virus detections were at low levels with influenza A(H1N1)pdm09, A(H3N2) and B viruses detected.
- In South-East Asia, influenza detections were at low levels with influenza A(H3N2) predominant.
- In the southern hemisphere, influenza activity remained low overall, although detections of influenza A(H3N2) continued to be reported in some countries in temperate South America.

COVID reports

WW data on test numbers, incidence and positivity rates can be found here by country

- <https://www.finddx.org/covid-19/test-tracker/>

Cumulative data on tests and cases can be found here:

- previously from: <https://coronavirus.jhu.edu/map.html>

US COVID Data

- <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>

Europe weekly report

- <https://covid19-surveillance-report.ecdc.europa.eu/>

Variants

- For those interested in variants check out the following:
- <https://covariants.org/per-country> (too many graphs for one this report – but interesting!)
- <https://www.ecdc.europa.eu/en/covid-19/situation-updates/variants-dashboard>
- https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fvariant-surveillance%2Fvariant-info.html
- <https://www.who.int/activities/tracking-SARS-CoV-2-variants>
- <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

Waste Water monitoring

- COVID-19 WBE Collaborative webpage: <https://www.covid19wbec.org/>
- COVID19Poops Dashboard: <https://www.covid19wbec.org/covidpoops19>

Influenza surveillance reports

Europe:

- <https://flunewseurope.org/>
- [Germany: https://www.rki.de/DE/Content/Infekt/NRZ/Konsiliar/RSV_PIV_hMPV/RSV_PIV_hMPV_node.html](https://www.rki.de/DE/Content/Infekt/NRZ/Konsiliar/RSV_PIV_hMPV/RSV_PIV_hMPV_node.html)
- [UK: https://www.gov.uk/government/statistics/national-flu-and-covid-19-surveillance-reports-2021-to-2022-season](https://www.gov.uk/government/statistics/national-flu-and-covid-19-surveillance-reports-2021-to-2022-season)

United States

- <https://www.cdc.gov/flu/weekly/index.htm>

WHO

- [Global update: https://www.who.int/teams/global-influenza-programme/surveillance-and-monitoring/influenza-updates](https://www.who.int/teams/global-influenza-programme/surveillance-and-monitoring/influenza-updates)

Respiratory Syncytial Virus (RSV) Surveillance Reports

USA/ CDC: <https://www.cdc.gov/surveillance/nrevss/rsv/index.html>

Germany:

https://www.rki.de/DE/Content/Infekt/NRZ/Konsiliar/RSV_PIV_hMPV/RSV_PIV_hMPV_node.html