



DIASORIN RECEIVES FDA DE-NOVO GRANT FOR THE SIMPLEXA® C. AURIS DIRECT ASSAY ON THE LIAISON® MDX INSTRUMENT

SIMPLEXA® C. AURIS DIRECT:

- IS A FIRST OF A KIND FDA DE-NOVO GRANTED ASSAY TO AID IN THE PREVENTION AND CONTROL OF *CANDIDA AURIS*, A RAPIDLY EMERGING MULTI DRUG-RESISTANT FUNGAL PATHOGEN COMMONLY FOUND IN HEALTHCARE SETTINGS;
- IS A REAL-TIME POLYMERASE CHAIN REACTION ASSAY RUN ON THE LIAISON® MDX INSTRUMENT FOR THE DIRECT IN VITRO QUALITATIVE DETECTION OF *CANDIDA AURIS* DNA FROM A SWAB OF OF PATIENTS SUSPECTED OF *CANDIDA AURIS* COLONIZATION;
- LEVERAGES THE SIMPLICITY OF THE LIAISON® MDX WORKFLOW, WITH MINIMAL SAMPLE PREPARATION AND RESULTS IN LESS THAN 2 HOURS WITH EXCELLENT CLINICAL PERFORMANCE.

Saluggia, Italy – July 16, 2024 – Diasorin (FTSE MIB: DIA) today announced that the Food and Drug Administration (FDA) has granted de-novo authorization for the Simplexa® *C. auris* Direct kit to test patients suspected of *Candida auris* colonization and aid in preventing potential spread in healthcare settings. This real-time polymerase chain reaction (RT-PCR) assay is used for the direct *in vitro* qualitative detection of *C. auris* DNA from a swab of axilla/groin from patients suspected of *C. auris* colonization, and detects the six *C. auris* clades that are circulating globally.

Run on the LIAISON® MDX, the easy-to-use, sample-to-answer system has a streamlined workflow yielding results in less than two hours.

C. auris is a challenge for healthcare facilities since patients may be asymptotically colonized, and it spreads easily in hospital environments and to other patients. Its colonization is a known risk factor for invasive infections which are associated with high mortality rates. *C. auris* continues to emerge and often does not respond to commonly used antifungal drugs. Because of this, the World Health Organization (WHO) and U.S. Centers for Disease Control and Prevention (CDC) have identified *C. auris* as a fungal pathogen of critical importance.

Responsible for outbreaks in more than 35 countries over the last decade and emerging as a significant healthcare concern, *C. auris* is considered to be an urgent antimicrobial resistance threat. Therefore, screening to identify colonized patients is key to implementing timely contact precautions and infection control measures to limit the spread of the organism within healthcare facilities and to prevent outbreaks. Traditional methods take several days to get results and often need to be sent out to a reference lab.

“The FDA de-novo authorization for the Simplexa® C. auris Direct kit fills a much-needed gap in C. auris molecular detection and uniquely positions Diasorin as the first molecular diagnostic vendor to commercialize a PCR test for the prevention and control of Candida auris infection in healthcare settings,” said Angelo Rago, President of Luminex. *“This de-novo molecular test is the first easy, fast, and moderate complexity assay empowering laboratories with diagnostic confidence in managing patients suspected of C. auris infection, thereby promoting better patient outcomes.”*

Carlo Rosa, CEO of Diasorin, commented *“With the launch of this new product in the field of molecular diagnostics, we confirm our strong position as a company focused on identifying diagnostic solutions for urgent, emerging and relevant clinical conditions through our positioning as a specialty player in diagnostics.”*



About Diasorin

Headquartered in Italy and listed at the Italian Stock Exchange in the FTSE MIB Index, DiaSorin is a global leader in the In Vitro Diagnostic (IVD) field and is active since 2021 in the Life Science business. For over 50 years, the Company has been developing, producing and marketing reagent kits used by diagnostic laboratories worldwide.

The Group operates in 5 continents through 39 companies, 4 branches, 10 manufacturing facilities and 9 research and development centers. The extensive diagnostic testing and Life Science offer, made available through continuous investments in research, positions DiaSorin as the player with the broadest range of specialty tests available within the diagnostic market, and identifies the Group as the “Diagnostic Specialist”.

More info at www.diasorin.com

FOR ADDITIONAL INFORMATION, PLEASE CONTACT:

INVESTOR RELATIONS

Riccardo Fava

Corporate VP Communication, ESG & Investor Relations
riccardo.fava@diasorin.com

Eugenia Ragazzo

Corporate Investor Relations & ESG Analyst
eugenia.ragazzo@diasorin.com