

DIASORIN LAUNCHES THE SIMPLEXA™ C. AURIS DIRECT ASSAY ON THE LIAISON® MDX INSTRUMENT IN ALL COUNTRIES ACCEPTING THE CE MARK

THE SIMPLEXA™ C. AURIS DIRECT ASSAY:

- AIDS IN THE PREVENTION AND CONTROL OF *CANDIDA AURIS*, A RAPIDLY EMERGING MULTIDRUG-RESISTANT FUNGAL PATHOGEN COMMONLY FOUND IN HEALTHCARE SETTINGS;
- IS A REAL-TIME POLYMERASE CHAIN REACTION ASSAY RUN ON THE LIAISON® MDX INSTRUMENT, WITH MINIMAL SAMPLE PREPARATION AND RESULTS IN LESS THAN 2 HOURS WITH EXCELLENT CLINICAL PERFORMANCE;
- IS AVAILABLE IN ALL COUNTRIES ACCEPTING THE CE MARK IN ACCORDANCE WITH IVD REGULATION 2017/746.

Saluggia, Italy – March 18, 2025 – Diasorin (FTSE MIB: DIA) announces the launch of its Simplexa™ *C. auris* Direct kit in all countries accepting the CE mark. The assay aids in the identification of patients suspected of *Candida auris* colonization to enable infection control in healthcare settings, and prevent potentially deadly infections in vulnerable patients.

This real-time polymerase chain reaction (RT-PCR) assay is used for the direct *in vitro* qualitative detection of *C. auris* DNA from a composite swab of axilla/groin from patients suspected of *C. auris* colonization, and detects all six *C. auris* clades identified globally. This targeted molecular diagnostic test is performed on the LIAISON® MDX, yielding patient results in less than two hours with excellent clinical performance.

C. auris is a global challenge for healthcare facilities since asymptomatically colonized patients can easily spread the fungus in hospital environments and to other patients. Furthermore, patient colonization is a known risk factor for invasive infections that are associated with high mortality rates.

C. auris infections are known to be resistant to one or more classes of antifungal drugs. Because of this, the World Health Organization, U.S. Center for Disease Control and Prevention, and European Centre for Disease Prevention and Control have all identified it 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.

“Diasorin is committed to develop impactful diagnostic solutions to combat deadly and emerging infections,” said Angelo Rago, President of Luminex. *“The Simplexa™ C. auris Direct kit fills a much-needed gap in C. auris molecular detection and will help to empower labs to easily, accurately and rapidly control and prevent Candida auris infections in healthcare settings”.*



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 35 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

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