

## To: Editors & Health Journalists Issued by: National Institute for Communicable Diseases Date: Saturday, 23 November 2024

## Outbreak of Alkalihalobacillus clausii bacteraemia related to the use of the Enterogermina probiotic in private-sector hospitals, Gauteng and North West provinces, March – October 2024

On 11 June 2024, the National Institute for Communicable Diseases (NICD), a division of the National Health Laboratory Service (NHLS), received notification from a pathologist in a private laboratory of an increase in bacteraemia cases of Alkalihalobacillus clausii (A. clausii) previously known as Bacillus clausii.

Following the notification, an investigation was conducted, collecting microbiological records of *A. clausii*-positive blood cultures from the reporting laboratory from January 2024 to October 2024. Over this period, 11 cases of *A. clausii* bacteraemia were identified in eight different hospitals across Gauteng and North West provinces. Most of the patients had reported using Enterogermina probiotics prior to the bacteraemia onset. Isolates from four cases and two open packets of Enterogermina probiotic used by the patients were sent to the NICD for whole genome sequencing. The investigation determined Enterogermina probiotic as the likely source for *A. clausii* bacteraemia.

A. *clausii*, is a non- pathogenic, spore forming Gram positive bacillus, which has demonstrated probiotic properties and significant therapeutic potential. It is commonly prescribed to manage gut dysbiosis and diarrhoea, including antibiotic-associated diarrhoea, by suppressing pathogenic bacteria and promoting anti-inflammatory responses. This species has been utilised in oral bacteriotherapy products like Enterogermina. It is generally safe for most populations, including children and immunocompromised individuals, though caution is needed in severely immunocompromised patients.

The NICD shared a detailed report with the reporting laboratory recommending that all pharmacists at hospitals with A. *clausii* bacteraemia cases notify the South African Health Products Regulatory Authority (SAHPRA) for further investigation. Hospitals with cases clustering by time and place should conduct further investigations to rule out a healthcare-associated source. Healthcare professionals and patients should be informed of this outbreak and educated on the safe use of probiotics including consideration of patients' immune status, contra-indications and side effects.

## For enquiries and interview requests, please contact: Media@nicd.ac.za



Chairperson: Prof Jeffrey Mphahlele CEO: Prof Koleka Mlisana Physical Address: 1 Modderfontein Road, Sandringham, Johannesburg, South Africa Postal Address: Private Bag X4, Sandringham, 2131, South Africa Tel: +27 (0) 11 386 6400 Fax: +27 (0) 11 882 0596 www.nicd.ac.za Practice number: 5200296