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FOR IMMEDIATE RELEASE

Trajan's customized kits supporting diagnosis of genetic disorders

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Trajan Scientific and Medical (Trajan) is pleased to support genetic diagnostic services via the Children's Hospital at Westmead (CHW), New South Wales, Australia.

CHW is part of the Sydney Children's Hospital Network (SCHN), the largest network of hospital and services for children in Australia. Their diagnostic and support services cover not only Sydney, but a large area of the Asia Pacific region, for example, accepting cases from Australia, New Zealand, Malaysia and Singapore.

Trajan has worked closely with CHW Neurochemistry and Biochemistry laboratories, to develop a customized kit to improve cerebrospinal fluid (CSF) sample collection during newborn screening for nonketotic hyperglycinaemia (NKH).

NKH is a genetic disorder that interferes with cellular metabolic processes. Early diagnosis and intervention is critical as NKH can be fatal, or affect many different organs causing severe problems with learning and development.

Within Trajan's customized CHW CSF Sampling Kit, CSF tubes are labelled to identify the required volume and indicate the specific test, and include an amber tube to ensure reduced light exposure to help maintain sample integrity.

Dr Sushil Bandodkar, Principal Scientist and Head, Biochemistry, The Children's Hospital at Westmead, said, "Having the customized CSF collection kits ready to go saves our team time from the collection stage through to analyzing the specimen in the laboratory."

"The prepared kits allow improved sample integrity." said Dr Bandodkar.

The CSF kits are made up in Trajan's clinical diagnostic packing facility based in Victoria, Australia. This is a clean monitored temperature-controlled environment, purpose-built to meet the needs of healthcare and pathology providers through the supply of TGA compliant customized diagnostic procedure packs or kits intended for our customer's in-house use.

By working with Trajan, laboratories can have specialized kits made up to required standard, saving administration time and money. Trajan supplies customized packs as per the customer's specification.

More information
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Photo: Analyzing the cerebrospinal fluid (CSF) specimen using UPLC in the laboratory. Shirley Alvarez, Hospital Scientist, the Children's Hospital at Westmead.

NOTES FOR EDITORS

1. Trajan Scientific and Medical

Trajan collaborates with academic and industry partners to develop and deliver innovative products. Together we will deliver breakthrough solutions to improve human wellbeing through biological, environmental or food related measurements. Our focus is on developing and commercializing technologies that enable analytical systems to be more selective, sensitive and specific - especially those that can lead to portability, miniaturization and affordability.

A 17,000 m^2 Ringwood site in Melbourne, Victoria, is home to Trajan's corporate headquarters and ISO accredited manufacturing operations. With around 400 staff worldwide across Australia, Europe, USA and Asia, Trajan serves customers in over 100 countries with highly specialized consumables and components used in scientific analysis and clinical applications.

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Trajan and recent changes from the Australian Therapeutic Goods Administration
Since 1 July 2017, the Australian TGA requires Australian laboratories that manufacture in-house in vitro diagnostic medical devices (IVDs) to meet regulatory requirements to legally supply their IVDs in Australia. In this context, supply means making the test available to clinicians and reporting results of the test.

Trajan is able to supply Australian TGA compliant procedure packs for clinical use, where the customer is not registering in-house IVDs directly with the TGA.

By working with Trajan, laboratories do not need to engage directly with the TGA, saving administration time and money on registering each IVD, or test component. Trajan supplies TGA IVD compliant procedure packs, tailored to specific tests.

Please refer to the www.tga.gov.au for further information regarding the relevant legislation; Therapeutic Goods Act 1989; Part 6A, Schedule 3, of the Therapeutic Goods (Medical Devices) Regulations 2002 (for Class 1- 3 in-house IVDs); and Part 1 or Part 6B, Schedule 3, of the Therapeutic Goods (Medical Devices) Regulations 2002 (for Class 4 in-house IVDs).

2. Sydney Children's Hospitals Network

The Sydney Children's Hospitals Network (SCHN) incorporates The Children's Hospital at Westmead, Sydney Children's Hospital, Randwick, Bear Cottage, the Newborn and pediatric Emergency Transport Service (NETS), the Pregnancy and newborn Services Network (PSN) and the Children's Court Clinic.

SCHN is the largest network of hospital and services for children in Australia. Each year the network services manage 51,000 inpatient admissions, 92,000 Emergency Department presentations, and over one million outpatient service visits.

www.schn.health.nsw.gov.au

Children's Hospital at Westmead Pediatric Pathology Services –Biochemistry and neurochemistry
The Children's Hospital at Westmead's (CHW) Biochemistry laboratory offer a comprehensive range of biochemistry services, including:

- Galactosaemia testing - Two red blood cell enzyme assays are performed: (1) galactose-1-phosphate uridyl transferase, to diagnose classical galactosaemia and (2) galactokinase to diagnose galactokinase deficiency in patients with cataracts of unknown cause. This is a state-wide service and works closely with Biochemical Genetics.
- Urinary PHPAA and histamine testing - PHPAA (p-Hydroxyphenyl-acetic acid) is a sensitive marker for bowel obstruction and bacterial overgrowth syndromes; while Histamine and its metabolite 1-methyl histamine are extremely useful in the diagnosis of systemic mastocytosis or diffuse cutaneous mastocytosis. This is a unique service offered to all states in Australia and neighboring countries.
- Urinary pterin and biogenic amine testing - Children with a positive Guthrie test for hyperphenylalaninaemia (PKU) require testing of urinary Pterins and biogenic amine testing to exclude tretrahydropterin deficiency due to GTPCH deficiency, 4-α-carbinolamine dehydratase and dihydropterine reductase deficiency. From 1988 this service is being performed for all states of Australia, New Zealand with some samples received from the Philippines and Malaysia.
- Sweat tests - CHW Biochemistry offers complete sweat collection and testing for paediatrics. Sweat chloride is determined for diagnosis of Cystic Fibrosis. CHW Biochemistry is experiencing an increase in the number of patient requests with diagnosed Cystic Fibrosis requesting a non-diagnostic sweat test to meet the PBS requirements for Ivacaftor (Kalydeco) therapy.

The CHW Australasian Paediatric Neurochemistry Laboratory is a highly specialized unit within Biochemistry which measures neurotransmitters, their metabolites, precursors and pteridine cofactors in cerebrospinal fluid and urine and receives samples from all states across Australia and nearby countries such as New Zealand, Singapore, and Malaysia.

These tests detect neurodegenerative, inflammatory central nervous system (CNS) diseases and movement disorders affecting the brain and spinal cord and inborn-errors of neurotransmitter biosynthesis and metabolism including defects or deficiencies in pteridine biochemistry (including DOPA responsive Dystonia, and Dystonia/Myoclonus Syndrome); tyrosine hydroxylase, aromatic amino acid decarboxylase, dopamine-beta-hydroxylase, monoamine oxidase and catechol-o-methyltransferase deficiencies.

The unit analyses dopamine and metabolites for detecting neuroblastoma and ganglioneuroma, noradrenaline, adrenaline and metabolites for detecting phaeochromocytoma and histamine for systemic mastocytosis. Special loading tests such as Phenylalanine and/or Tetrahydropterin challenge testing is also conducted in the Neurochemistry Laboratory for the differential diagnosis of Pterin deficiencies and classical PKU.

http://www.schn.health.nsw.gov.au/about-us/about-the-childrens-hospital-at-westmead