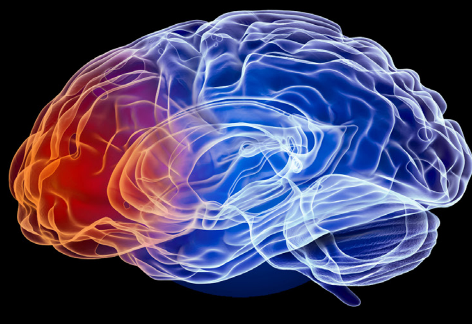
DRG Instruments GmbH

Automated, Accessible, Accurate, and Affordable ER Diagnostic CLIA Tests for Mild Traumatic Brain Injury (mTBI)

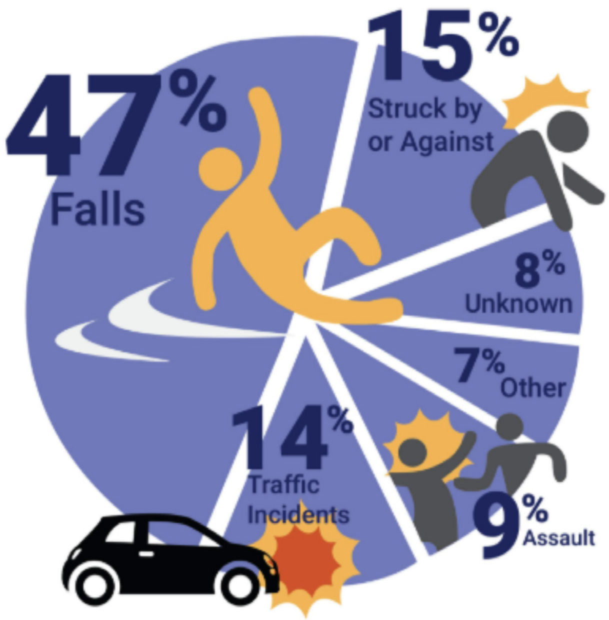


Introduction

How Does TBI Occur?

The human brain can be injured by a collision, rapid acceleration or rapid deceleration.

Leading Causes of TBI



TBI Classifications

TBI can be mild, moderate or severe based on the extent of the damage to the person's physical and cognitive capacity. Severe cases can result in life-threatening pressure on the skull or reduce blood flow to the brain.

Classification System for Traumatic Brain Injury

LEVEL	Duration Of Unconsciousness	Glasgow Coma Scale	Post-Traumatic Amnesia
Mild	<30 Minutes	13-15	<24 Hours
Moderate	30 Minutes - 24 Hours	9-12	1-7 Days
Severe	>24 Hours	3-8	>7 days

Why TBI Blood Tests?

- **UCH-L1 and GFAP can be detected in 1 hour after trauma.**[1] A long wait for CT scan can result in delay of diagnosis, treatment, and path to recovery due to long turnaround times. A draw of patient's blood can provide quicker path for treatment.
- **Mild TBIs generally don't show up on CT scans** or MRIs. GFAP and UCH-L1 levels can be detected via blood test.
- **Prevents** unnecessary radiation exposure.

1. JAMA Neurol. 2016;**73**(5):551-660

Test Background, Device for processing: *DxDATA™* and Ordering Information

2-2025

For more information
or to place an order, please call us at
+49(0)6421/1700-0 or email drg@drg-diagnostics.de

DRG NEUROSCIENCE

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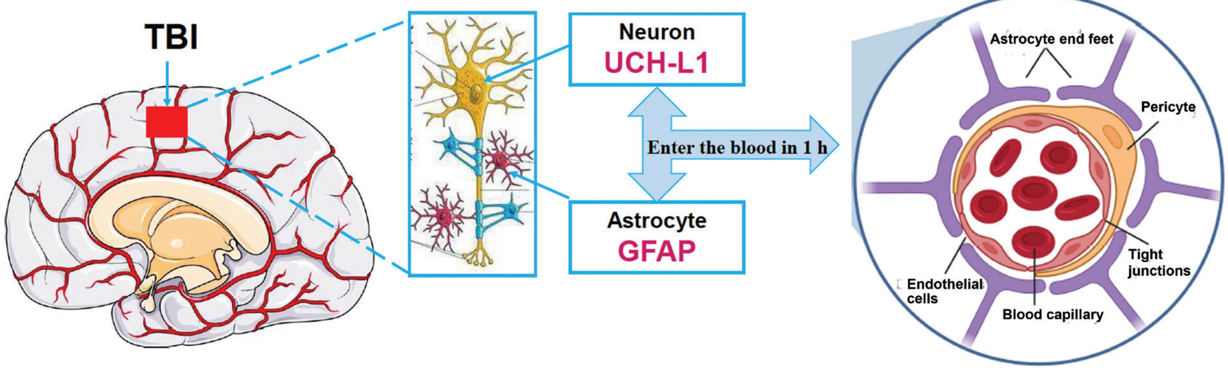
TBI Biomarker Background



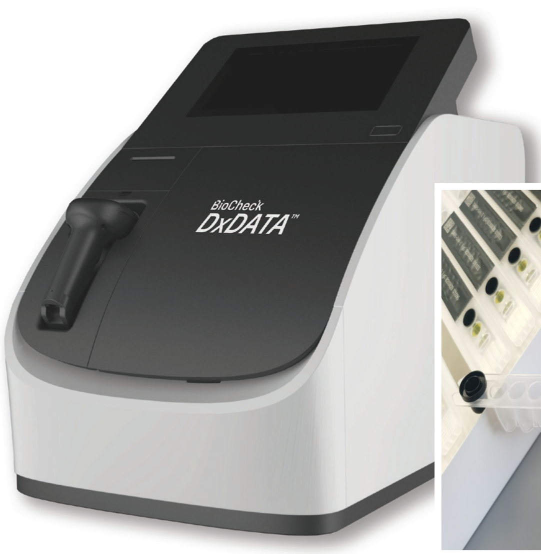
Brain injury biomarkers such as GFAP and UCH-L1 have effectively shown to help health care providers in providing immediate standard of care to evaluate and treat patients.

GFAP (Glial Fibrillary Acidic Protein)

- **Role in TBI:** GFAP is released when astrocytes are damaged, making it a specific marker for astroglial injury, which occurs in moderate to severe TBI. Blood levels of GFAP increase soon after injury and remain elevated longer than UCH-L1, providing a longer window for detection.

UCH-L1 (Ubiquitin C-terminal hydrolase-L1; (PGP 9.5))

- **Role in TBI:** UCH-L1 is released into the bloodstream following neuronal injury, making it a reliable marker for neuronal damage in TBI. Elevated levels of UCH-L1 in the blood can be detected within hours after an injury, helping clinicians diagnose mild to moderate TBI and differentiate it from non-brain injuries.



The ***DxDATA™*** is an easy-to-use, bench-top automated discrete loading chemiluminescence enzyme-linked immunosorbent assay (CLIA) and magnetic particle separation analyzing system. It uses indirect chemiluminescence based on a chemiluminescent substrate (APS-5) and alkaline phosphatase for qualitative or quantitative testing.

SPECIFICATIONS:

- **Size:** 400 (W) * 610 (D) * 550 (H) mm
- **Weight:** 35 kg
- **Sample throughput:** 8 channels - one-test-cartridges
- **Sample type / Sample volume:** Serum / 120 µl
- **Data storage:** Patient data 100,000 samples (tests)
- **Screen:** LCD touchscreen
- **Detection time:** 30 minutes
- **LIS/HIS:** Unidirectional

Ordering Information

Catalog #	Description	Specimen	CE Status
DXDA-1003-10	GFAP CLIA Kit	Human Serum	CE
DXDA-1004-10	UCH-L1 CLIA Kit	Human Serum	CE
DXD-0001	*DxDATA™* Automated Chemiluminescent Immunoassay Analyzing System		CE

To learn more about the test availability in your region or more information about DRG's mTBI Tests, please contact our Sales Representative or email us at drg@drg-diagnostics.de.

Test is intended to be used in a clinical laboratory setting by a healthcare professional and to be used in conjunction with other clinical information. For patients 18 years of age or older.

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