



Changing Clinical Microbiology

The MALDI Biotyper[®] CA System

Clinical application for identification of microorganisms

Innovation with Integrity

US-IVD

In microbiology, speed and accuracy matter



A powerful technology for better results

To help answer key challenges in Clinical Microbiology, Bruker has utilized its many years of experience to create the truly groundbreaking MALDI Biotyper CA System. This revolutionary technology has allowed both large reference laboratories and small hospital laboratories to achieve reliable and efficient identification of clinically significant gram-negative bacteria, gram-positive bacteria, and yeast within an easy to operate, yet powerful benchtop analyzer.

- Accuracy comparable to Nucleic Acid Sequencing
- Much faster than traditional methods
- Cost-effective
- Robust and easy to use
- A true benchtop system
- Easy to implement
- Optional workflow improvement tools

Identifying microorganisms by their molecular fingerprint

The MALDI Biotyper CA System identifies microorganisms using MALDI-TOF (Matrix-Assisted Laser Desorption/Ionization Time-of-Flight) mass spectrometry to measure a unique proteomic fingerprint of an organism. Specifically, the MALDI Biotyper CA System measures highly abundant proteins that are found in all microorganisms, and takes advantage of their specific differences.

The characteristic patterns of these highly abundant proteins give the unique fingerprint of an organism and are used to reliably and accurately identify a particular microorganism by matching the respective pattern with an extensive FDA-cleared reference library.

Bruker continues to improve clinical isolate coverage achieving greater than 98% correlation with sequencing.

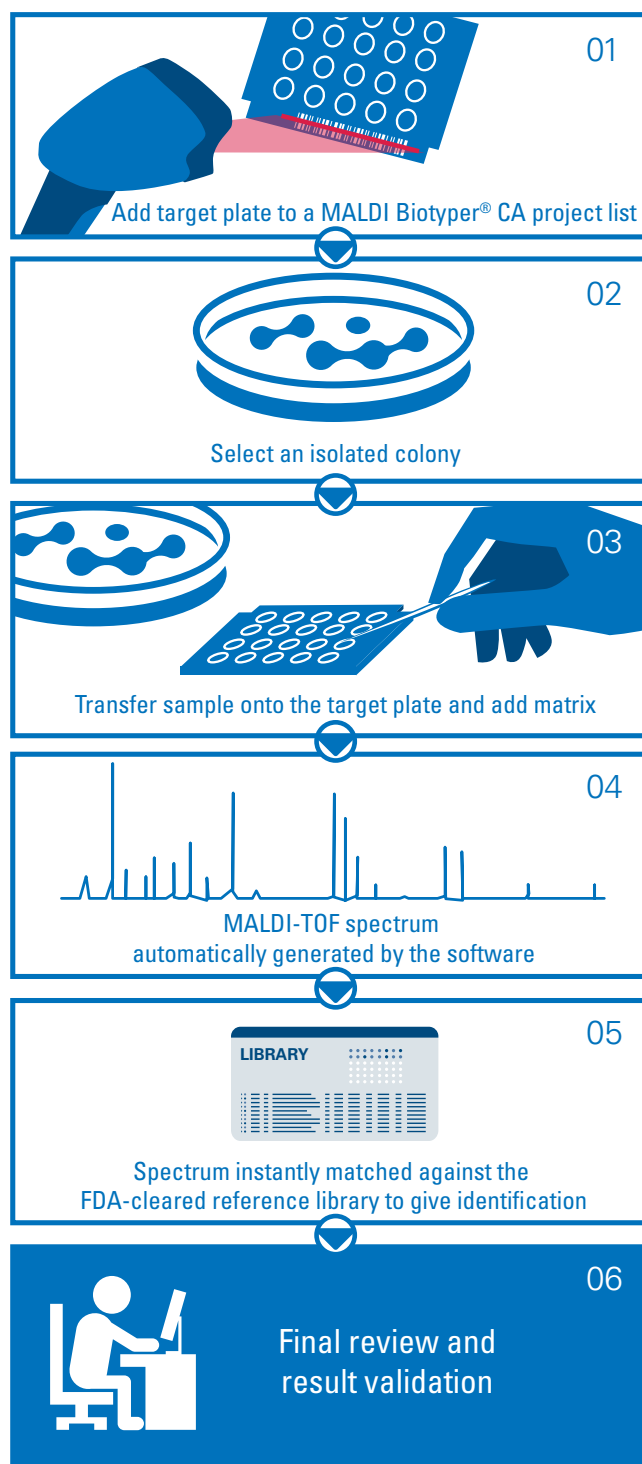
A simple procedure for a sophisticated platform

Innovative design leads to enhanced performance and productivity

The MALDI Biotyper CA System workflow has been designed to be efficient and easy. No previous experience with mass spectrometry is required. As shown, the fully traceable workflow has been streamlined and requires only a few simple steps to generate high quality microorganism identifications.

Typically, no more than an isolated single colony from a culture is required. The entire process needs only a few minutes to complete.

Our dedicated microbiology software automates the process of acquiring the mass spectrum and performing the match against the extensive FDA-cleared reference library. The results, presented using a 'traffic light' color scheme, are effortless to interpret.



Easy-to-use software dedicated to microbiology

In just a few steps, the simple-to-use software guides users through the set-up of samples for analysis.

BTS	Spot	Name	Id	Description
<input type="checkbox"/>	A1	A1	4548554	
<input type="checkbox"/>	A2	A2	4548555	
<input type="checkbox"/>	A3	A3	4548556	
<input type="checkbox"/>	A4	A4	4548557	
<input type="checkbox"/>	A5	A5	4548558	
<input type="checkbox"/>	A6	A6	4548559	
<input type="checkbox"/>	A7	A7	4548560	
<input type="checkbox"/>	A8	A8	4548561	
<input type="checkbox"/>	A9	A9	4548562	
<input type="checkbox"/>	A10	A10	4548563	
<input type="checkbox"/>	A11	A11	4548564	
<input checked="" type="checkbox"/>	B1	B1	BTS	
<input checked="" type="checkbox"/>	B2	B2	BTS	

Automatic calibration and quality control check

The MALDI Biotyper CA System is automatically checked using US IVD Bacterial Test Standard (BTS) before each use. When the check is successful, the system automatically begins the measurement process.

Target Position	Test Organism Label	Organism Identification	log (score) Value
A1	4548554	Enterococcus faecalis	2.45
A2	4548555	Proteus vulgaris_group	2.25
A3	4548556	Proteus mirabilis	2.62
A4	4548557	Candida albicans	2.19
A5	4548558	Pseudomonas aeruginosa	2.10
A6	4548559	Escherichia coli	2.38
A7	4548560	Escherichia coli	2.29
A8	4548561	Klebsiella pneumoniae	2.17
A9	4548562	Enterococcus faecium	2.32
A10	4548563	Dermabacter hominis	2.37
A11	4548564	Trueperella bernardiae	2.47

Clear identification results on the report

After the acquisition of the spectral data has been completed, a report is generated. The result for each sample is clearly listed under 'Organism Identification' accompanied by the resulting score and appropriate 'traffic light' color scheme.

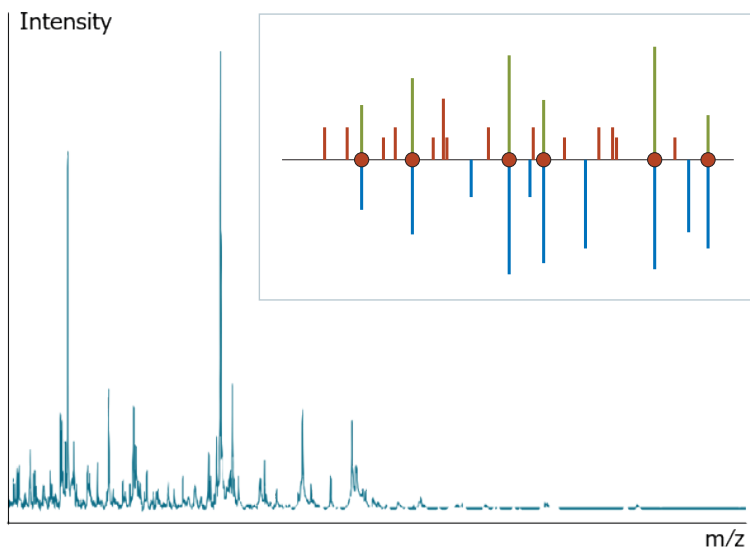
Robust and accurate identification based on an extensive reference library

FDA-cleared reference library

The MALDI Biotyper CA reference library includes 549 microbial species including 236 gram-positives, 269 gram-negatives, and 44 yeasts, including *Candida auris*.

Non-clinically validated library

The non-clinically validated library covers more than 3,400 reference strains that have not been clinically validated. In the interest of public healthcare, these organisms are specially marked and displayed in the MALDI Biotyper result report in order to direct the required laboratory method for identification. These results are not automatically transmitted to the laboratory information system.



The main spectra concept capturing true biological variability

Reference library entries in the MALDI Biotyper CA System are stored as Main Spectra (MSP). These MSPs are based on multiple measurements of a single defined strain to ensure that the true biological variability of an organism has been captured.

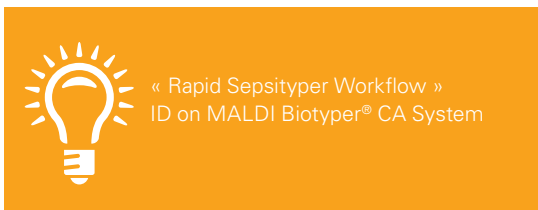
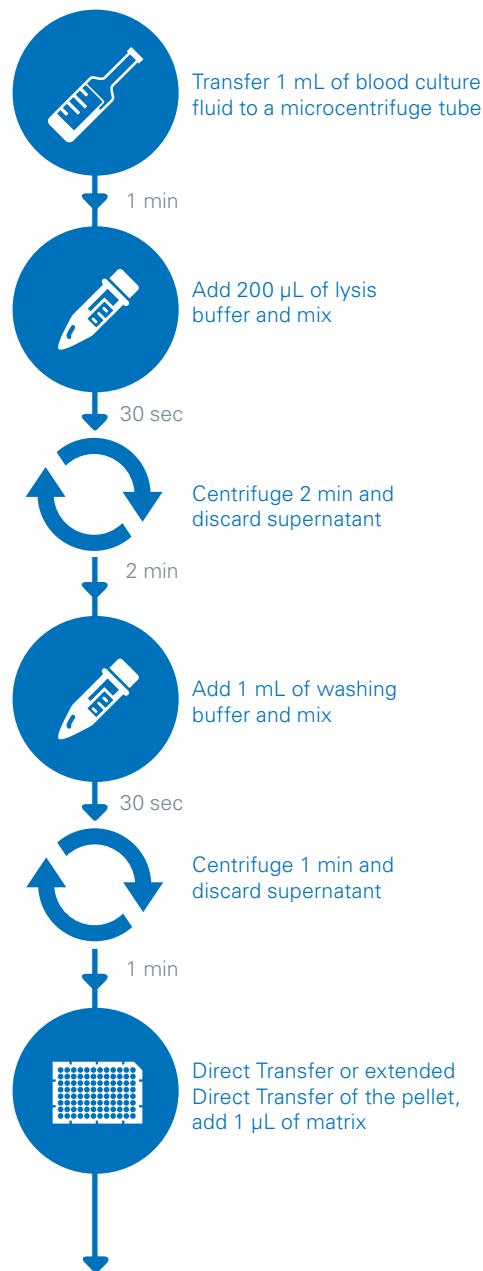
Unknowns are then compared to the FDA-cleared MSP library using a superior pattern-matching approach. This includes peak positions and intensities, ensuring the highest possible levels of accuracy and reproducibility across the complete range of microorganisms.

Straightforward result interpretation

The spectrum of the unknown test organism, acquired through the MALDI Biotyper CA System Software, is electronically transformed into a peak list. Using a biostatistical algorithm, this peak list is compared to reference peak lists of organisms in the reference library and a log(score) value between 0.00 and 3.00 is calculated. Interpretation is made easy by the use of a 'traffic light' color scheme.

Range	Interpretation	Color
2.00 - 3.00	High Confidence Identification	Green
1.70 - 1.99	Low Confidence Identification	Yellow
< 1.70	No Organism Identification Possible	Red

When every minute counts



If no ID:
Standard extraction,
spot 1 µL of extract onto the
MALDI target, add 1 µL of
matrix

10 min



ID on MALDI Biotyper®
CA System
“Full Sepsityper Workflow”

MBT Sepsityper® Kit US IVD

For rapid microorganism identification direct from positive blood culture using the MALDI Biotyper® CA System.

The FDA-cleared MBT Sepsityper® Kit US IVD is used in conjunction with the Bruker MALDI Biotyper CA System, allowing highly confident species level identification (ID) direct from positive blood culture.

A rapid, accurate and cost-effective micro-organism ID becomes available within 15-20 minutes after the blood culture alerts positive and requires only 10 minutes of hands-on time to prepare the sample. When compared to traditional methods, ID results can be reported up to 48 hours earlier to critical care providers.



Key features

Rapid identification

- Less than 10 minutes hands-on time eliminating the need for batching
- 15 -20 minutes overall identification time
- Complete identification in the same amount of time as Gram stain result

» Dr. Elisabeth C. Shearon

Medical Director at Alverno Laboratories, Hammond, IN

"Rapid Sepsityper identification has been instrumental in terms of patient care. Especially in critically-ill patients, the improved turnaround time allows disease specific treatment which conserves healthcare resources and, most importantly, improves patient outcomes."*



Accurate, specific and efficient

- Analyzed using the world renowned MALDI Biotyper CA System
- Identifies all organisms contained within the current and future versions of the MALDI Biotyper CA System Reference Library, which includes bacteria and yeast
- Accuracy comparable to nucleic acid sequencing

» Ike Northern

CompuNet Clinical Laboratory, Director of Infectious Disease Testing and Immunology, Dayton, OH

"I think a lot of laboratories are realizing that they need to use MALDI-TOF MS technology for microbial identification. Many are now making this investment when they recognize the long-term cost benefits. The MBT Sepsityper Kit US IVD will be the next step for a lot of clinical microbiology laboratories. Many are currently using multiplex PCR tests but once you have the MALDI Biotyper instrument, it's more cost-effective to use the MBT Sepsityper Kit US IVD than large PCR panels."*



Improves patient care and economic benefits

- Complete ID available up to 48 hours earlier than traditional ID methods
- Rapid ID promotes Antibiotic Stewardship intervention
- Early confirmation of skin contaminants eliminates further unnecessary treatment and testing

» Dr. Steven D. Burdette

Medical Director, Antimicrobial Stewardship Miami Valley Hospital and Premier Health, Dayton, OH

"The MBT Sepsityper Kit data has allowed us to adjust antibiotic therapy according to our local antibiogram. This, at times, has allowed us to narrow or stop certain antibiotic treatments while in other cases, it has allowed us to escalate antibiotic coverage pending sensitivity data. It has become a crucial tool for our Antimicrobial Stewardship team."*



* All quoted early adopter customers have validated the research-use-only (RUO) version of the MBT Sepsityper kit as a laboratory-developed test (LDT) prior to the FDA-clearance of the MBT Sepsityper Kit US IVD.

The best technology from the experts in mass spectrometry

A platform suited to your needs

Being the leader in MALDI-TOF technology, it is of great importance to Bruker to design robust, compact, high performance platforms intended for extensive and routine usage in the microbiology laboratory.

Bruker offers laboratories the opportunity to choose the MALDI-TOF mass spectrometer that best fits their needs:

- The **MALDI Biotyper sirius one CA System** with Bruker's proprietary lifetime* smartbeam™ solid state laser technology at 200 Hz repetition rate and positive ion mode. System improvements, including the newest electronics and high performance vacuum system, generate fast target exchange times for accelerated time-to-result - even faster than before.
- The **MALDI Biotyper sirius CA System**, with the same innovative improvements, smartbeam™ 200 Hz laser and positive as well as negative ion detection. The additional capability of analysis in negative ion mode broadens the research applications, such as the analysis of lipids (the negative ion mode is for Research Use Only).

Resolution optimized for reliable profile matching

Overall, the resolution is an important performance parameter in MALDI-TOF mass spectrometry. A high resolution is desired for more precise analysis of samples, as it refers to the ability to distinguish between two closely spaced peaks in a mass spectrum. Thanks to Bruker's patented PAN™ resolution, the compact MALDI Biotyper achieves an optimal resolution over the relevant mass range of the mass spectral profile acquired from the unknown microorganisms. This accuracy is crucial when it comes to profile matching with the multiple reference spectra, for reliable identification of microorganisms.

Highly reproducible results

The quick and simple US IVD Bacterial Test Standard quality check performed before each run ensures the highest standard of run-to-run reproducibility.

Continuous operation

The integrated ion source cleaning permits continuous high performance with minimized maintenance requirements.

Cleaning the source using the separate IR-laser is performed easily under push-button operator control.



Compact benchtop systems - no performance compromise

True benchtop solutions

Low-noise operating systems with low weight and requiring less than 3 feet of counter space offer flexibility in meeting laboratory needs for compact system solutions. Both systems need only a 110V electrical supply which results in very minimal heat output.

	MALDI Biotyper sirius one CA System	MALDI Biotyper sirius CA System
Laser	Bruker's proprietary lifetime* smartbeam laser <ul style="list-style-type: none"> ■ 200 Hz repetition rate ■ ~400 samples/hr ■ 500 million laser shots 	
Polarity	Positive ion mode only	Positive and negative** ion mode
Mass range	0-500.000 Da; with MALDI Biotyper applications focused to 2.000-20.000 Da for microorganism identification	
Vacuum system	Oil-free membrane pre-vacuum pump and high capacity turbomolecular pump <ul style="list-style-type: none"> ■ high pumping capacity, which in combination with a clever source design results in very fast target exchange ■ minimal downtime after maintenance 	
Other features	LED strip to remotely observe system status Perpetual Ion Source™ with IR-laser self-cleaning functionality Whispermode™ <60 dB under normal operating conditions Oil-free membrane pre-vacuum pump and turbo pump Patented PAN™ technology for high mass resolution over a wide mass range Voltage: 110 V	
Dimensions & Operating Parameters	L x W x H: 500 x 710 x 1070 mm / 19.7 x 28.0 x 42.2" Net weight: 75 kg / 165.4 lb Noise: < 60 dB Temp Range: 16 - 30°C / 61 - 86°F Operating Humidity: 20 - 75%, non-condensing	

* Lifetime means: 500 million laser shots or seven years (whichever occurs first)

** Negative ion mode is for Research Use Only

MALDI Biotyper CA System overview

Benchtop MALDI-TOF system

- **MALDI Biotyper sirius one CA System,**
with 200 Hz smartbeam™ laser and positive ion mode
or
- **MALDI Biotyper sirius CA System,**
with 200 Hz smartbeam™ laser and positive and negative
ion detection (the negative ion mode is for
Research Use Only)

Routine identification of gram +/- bacteria, yeasts

Software

- MALDI Biotyper CA System
Software

Consumables

- US IVD 48 Spot target
- MBT Biotarget 96 US IVD
- US IVD Bacterial Test Standard
- US IVD HCCA portioned

Accessory

- MBT Shuttle ergonomic
target holder

Identification directly from positive blood cultures (optional)

Consumables

- MBT Sepsityper® Kit US IVD

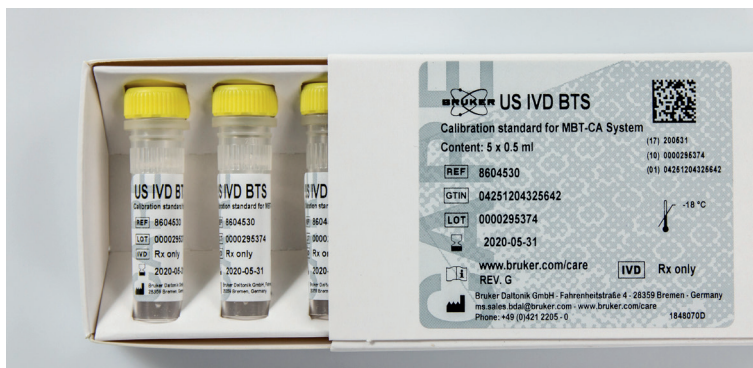


MBT CA System consumables

US IVD Bacterial Test Standard (BTS)

The BTS is an *E. coli* extract spiked with two high molecular weight proteins and has been developed for the quality control process of the MALDI Biotyper CA System. Its specific composition covers the entire mass range of proteins used by MALDI Biotyper CA System for precise identification of microorganisms.

Content: One box consisting of 5 tubes providing 50 µL per tube / Part No. 8604530



US IVD HCCA (alpha-Cyano-4-hydroxycinnamic acid) Matrix

The instant HCCA matrix enables easy and convenient preparation of HCCA matrix solutions. The matrix is soluble in standard organic solvent, easy to handle, and enables highly sensitive measurements.

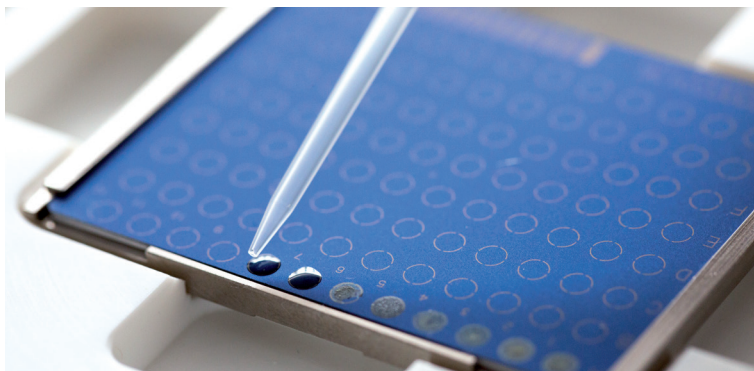
Content: One box consisting of 10 tubes providing 250 µL per tube / Part No. 8604531



Disposable MBT Biotargets

The ready-to-use disposable MBT Biotargets provide 96 positions and a unique barcode for full traceability in paperless workflows.

Disposable MBT Biotargets offer the same level of performance as reusable MALDI target plates without the need for time-consuming cleaning.



MBT Biotarget 96 US IVD

Set of 20 individually barcoded disposable 96 position MALDI target plates /
Part No. 1840380

MSP adapter for MBT Biotarget 96

Adapter required to use MBT Biotargets with MALDI Biotyper systems /
Part No. 8267615

MBT Sepsityper® Kit US IVD

The MBT Sepsityper Kit US IVD contains all reagents and consumables required for microorganism isolation from 50 positive blood culture samples.

MBT Sepsityper Kit US IVD /
Part No. 1867565

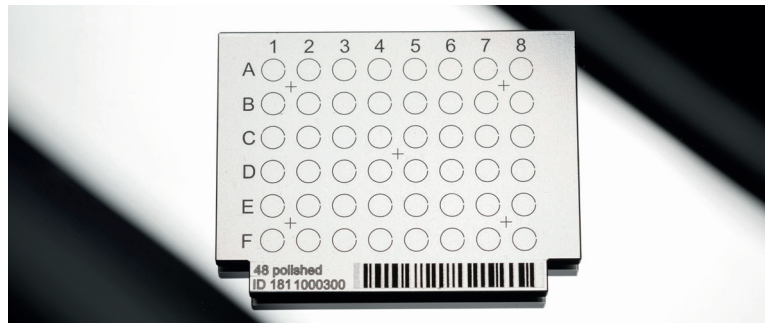


MBT CA System accessories

US IVD 48 Spot Target

Reusable polished steel target with barcode for MALDI-TOF mass spectrometry providing 48 sample spots. The barcode supports full traceability in paperless workflows.

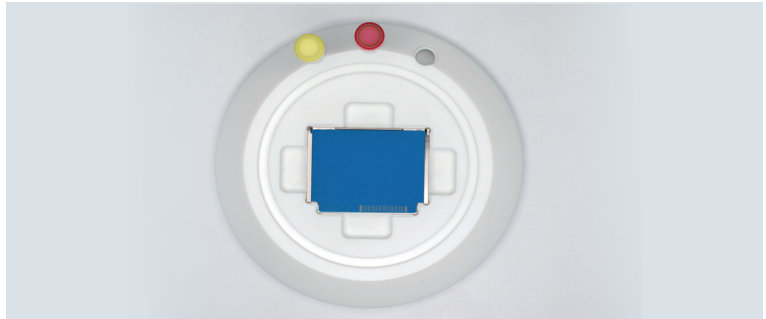
One target / Part No. 8604532



MBT Shuttle Target Holder

The MBT Shuttle target holder is used to securely hold a US IVD 48 Spot Target or MBT Biotarget 96 US IVD during the sample preparation process. The secure grip, non-slip rubber feet and ergonomic form make sample preparation easier.

One target holder / Part No. 1847302





THE ORIGINAL
Often imitated, never duplicated

Only for sale in the USA and Puerto Rico.

IVD

Rx ONLY

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