

Excellence

in Diagnostic Products



US PROFESSIONAL & US RETAIL
PRODUCT CATALOG / 2020

	Introduction	1 - 2
---	---------------------	-------

	OnCall®	3 - 6
---	----------------	-------

Diabetes Care
Blood Glucose Monitoring Systems
Lancing Devices
Bluetooth Adapter & Apps
Data Management Software

	Mission®	7 - 11
---	-----------------	--------

Hematology
Lipids
Coagulation
Urinalysis
Alcohol Testing

	HealthyMe®	10
---	-------------------	----

Urinalysis

	CentriVet®	12
---	-------------------	----

Veterinary Diagnostics

Introduction



Hangzhou, China



San Diego, California USA

For over 23 years, ACON has led the way in making high quality diagnostic and medical devices more affordable to people all around the world. In fact, the ACON name is well known in over 130 countries.

Headquartered in San Diego, California, the US office is the center of strategic management, administration, business development, innovative research and development. Our state of the art manufacturing facility located in Hangzhou, China is ISO13485: 2016 certified, FDA registered, and has been inspected by US FDA.

Our current product lines include Diabetes Care, Clinical Chemistry (Urinalysis and Point of Care Tests), Immunoassay, (EIA/ELISA) and Allergen. We also have a number of new products in the pipeline for introduction in the future.

Disclaimer:

Some products in this brochure may not be available in all countries. Please consult with your local ACON sales representative for details.

ACON Timeline

1996

ACON was founded in Bethlehem, PA, USA. ACON operated in a 27,000 sq. ft. manufacturing facility.

2001

Increased its manufacturing facility to 150,000 sq. ft. with more than 1,500 employees.

2009

Expanded product lines. ACON sold the LF rapid diagnostic business in Asia, the Middle East, Africa and Latin America. ACON continued to expand its business in Diabetes Care, Clinical Chemistry, and Immunoassay.

2016

Launched the PT/INR coagulation monitoring system in Europe and Latin America.

Your **Trusted** Partner

ACON works strategically with its sister companies to produce high quality medical products that meet and exceed the customers exacting quality expectations.

We are committed to continuously monitoring our quality systems to ensure their effectiveness and compliance to all applicable regulatory and quality requirements. Exceeding customer expectations and maintaining customer loyalty are our top priorities.

1999

Moved to San Diego, California, USA

2006

Launched new product lines. ACON sold the lateral flow (LF) rapid diagnostic business in the US, Europe, Canada, Israel, Japan, Australia, and New Zealand. ACON launched new product lines including Diabetes Care, Clinical Chemistry, and Immunoassay.

2014

Expanded and moved to a larger facility for manufacture, R&D and business development. Our new 70,000 sq. m (750,000 sq. ft.) facility includes state of the art manufacturing equipment to supply the growing demand of the global diagnostic market. The new facility will also allow our R&D and business development teams to expand, enabling ACON to develop more innovative products to meet our customer's needs worldwide.

2018

Launched the On Call® Care Alliance platform allowing healthcare providers and care teams to track, manage, and engage patients remotely.

2019

2019 – Launched On Call® Extra Mobile and On Call® Extra Voice blood glucose monitoring systems to the International markets. Launched On Call® Express Mobile and On Call® Express Voice blood glucose monitoring systems to the US market.

On Call® key product features



Strip Ejector

Allows the safe disposal of used test strips without contact.



Meter Backlight and Strip Port Light

Allows to test in dark environments and aids the visually impaired to read the display clearly.



Hypo, Hyper and Ketone Warnings

Alerts users to preset levels and reminds users to take the necessary actions.



Test Reminders

Maintain regular testing and insulin therapy routines on schedule.



Meal Markers

Easily monitor before and after meal results.



Data Averaging

Allows for quick access to trends in blood glucose levels.



Data Management

On Call® Diabetes Management Software available via USB cable connected from meter to a PC.



On Call® Bluetooth Adaptor

Allows users to wirelessly transmit glucose results to the On Call Care Alliance App for use with the On Call Care Alliance Remote Patient Monitoring Program.



Bluetooth Integrated

This meter has integrated Bluetooth® technology and does not require an adaptor or cable for use with the On Call Care Alliance Remote Patient Monitoring Program, the On Call Care Alliance App for iOS/Android.



On Call® Care Alliance

A Remote Patient Monitoring System that allows users to have a team of individuals wirelessly access blood glucose data including results and trends through the On Call Care Alliance Web Portal or the On Call Care Alliance App for iOS and Android.



On Call® Express Voice

Features audible instructions to assist the user from set up to testing.

En ISO 15197:2015

ISO 15197 is the International Standard that specifies requirements for in vitro blood glucose monitoring systems for self-testing in managing diabetes mellitus. All of the On Call meters meet the new ISO 15197:2015 standard shown below.*

En ISO
15197:2015
(new)

95% of measured glucose values should fall within either ± 0.83 mmol/L ($15 \pm$ mg/dL) of standard measurement procedure (YSI) at glucose concentrations < 5.55 mmol/L (< 100 mg/dL) or within $\pm 15\%$ of glucose concentrations ≥ 5.55 mmol/L (≥ 100 mg/dL).

ISO
15197:2003
(previous)

ISO 15197:2003 (previous): 95% of measured glucose values should fall within either ± 0.83 mmol/L ($15 \pm$ mg/dL) of standard measurement procedure (YSI) at glucose concentrations < 4.2 mmol/L (< 75 mg/dL) or within $\pm 15\%$ of glucose concentrations ≥ 4.2 mmol/L (≥ 75 mg/dL).

*Data on file

Diabetes Care



510(k) Cleared
and CLIA Waived

On Call® Pro

SPECIFICATIONS & FEATURES

- 0.4µL - Sample size
- Results in 4 seconds
- 75 – 60% Hematocrit Range
- Auto-coding
- GOD Enzyme, no interference from maltose, galactose, etc.
- 300 test memory

✓ Alternate site testing (forearm, palm)



510(k) Cleared
and CLIA Waived

On Call® Express II

SPECIFICATIONS & FEATURES

- Accuracy and Affordability in One System
- Audible fill detection
- Apply a second drop of blood within 3 seconds to avoid wasted strips
- 500 test memory with date and time
- 7, 14, 30, 60 and 90 day averaging
- Results can be marked as pre or post-meal

24/7 Support: 1-800-838-9502

Reliable: Clinically Proven Accuracy

Fast: 4 Second Testing

Less Pain: Tiny 0.4 µL Sample



510(k) Cleared
and CLIA Waived

On Call® Express Voice

SPECIFICATIONS & FEATURES

- 0.4µL – Sample size
- Results in 4 seconds
- Audible instructions to assist the user from set up to testing
- Tactile features designed for easy navigation
- Uses current On Call Express test strips
- 25 – 60% Hematocrit Range
- Auto-coding
- Apply a second drop of blood within 3 seconds to avoid wasted strips
- 500 test memory with date and time



510(k) Cleared
and CLIA Waived

On Call® Express Mobile

SPECIFICATIONS & FEATURES

- 0.4µL – Sample size
- Results in 4 seconds
- Bluetooth enabled for wireless data management
- Auto-sync via Bluetooth to On Call Care Alliance mobile apps
- Uses current On Call Express test strips
- 25 – 60% Hematocrit Range
- Auto-coding
- Apply a second drop of blood within 3 seconds to avoid wasted strips
- 500 test memory with date and time



Advanced

Biosensor Technology
for Fast and Accurate Glucose Testing

- Auto calibration circuitry inside every strip
- Accurate results in just 4 seconds with only a 0.4 µL blood sample
- Less painful testing from palm and forearm

Diabetes Care

Lancing Device & Lancets

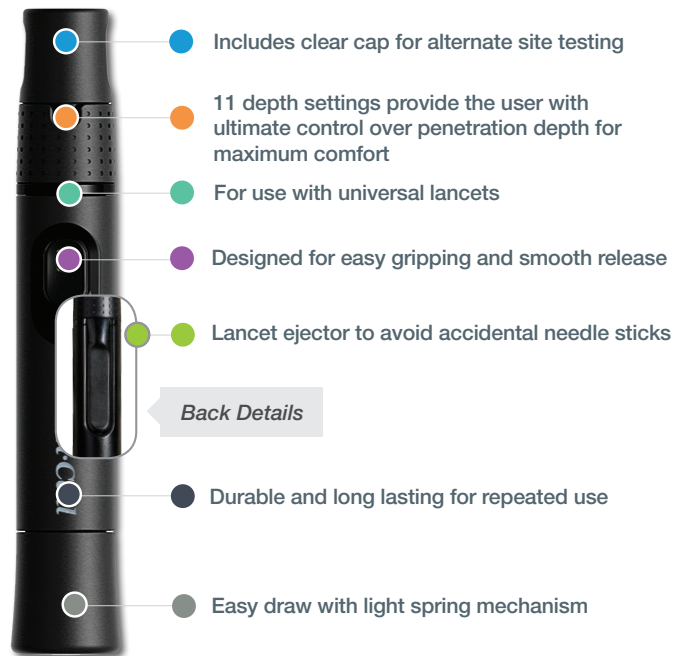
On Call® Stealth

SPECIFICATIONS & FEATURES

- Ergonomically designed for one hand operation
- Improved comfort for easy blood sample collection
- Built in ejector for safe and easy testing
- Color safety indicator to show lancet is loaded
- Eleven adjustable depths for personal comfort

9/10 PATIENTS PREFER ON CALL® STEALTH

REDUCE PAIN WITH A
TRI-BEVELED TIP.
FITS MOST LANCING
DEVICES.



On Call® Safety Lancets

SPECIFICATIONS & FEATURES

- Pressure activated safety lancets
- Needles automatically retract to ensure reliable patient protection
- Designed for single-use only to prevent re-use
- Various gauges and depths available for different blood volumes
- Available in 21G and 28G



SAFETY LANCETS I 21G, 28G

On Call® Lancets

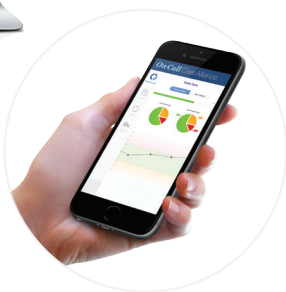
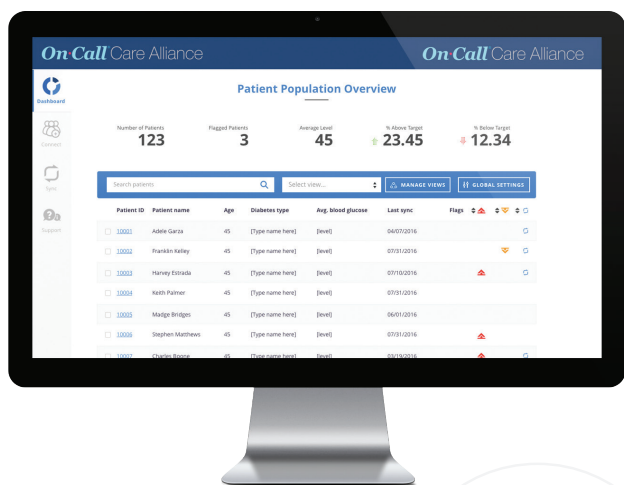
SPECIFICATIONS & FEATURES

- Available in both 30 and 33 gauge
- Smooth tri-bevel needle tip for a comfortable sampling experience
- Sterilized by gamma-radiation
- Versatile with most lancing devices



LANCETS 30G, 33G

Diabetes Care | Data Management



On Call® Care Alliance

SPECIFICATIONS & FEATURES

HEALTHCARE PROFESSIONALS ONLY:

- Track each patient individually, or create custom groups
- Receive alerts for customized events in each patient's glucose history
- Pinpoint problematic trends and patients requiring treatment adjustments

HEALTH CARE PROVIDERS ONLY:

- All data is stored securely on a HIPAA-compliant server
- Patient glucose data can be added in-office or from home
- Compatible with select On Call Blood Glucose Meters
- Web portal available on PC and mobile app available for Android and iOS



On Call® Bluetooth Adapter

SPECIFICATIONS & FEATURES

- For the wireless transfer of glucose readings from your On Call® meter to a mobile device
- Bluetooth 4.0 low energy technology
- Compatible with select On Call Blood Glucose Meters
- Compatible with On Call® Care Alliance



On Call® PC Software

SPECIFICATIONS & FEATURES

- Both home and professional editions available
- Customizable charts and graphs
- Compatible with all On Call® meters



Clinical Chemistry

The Mission® brand of point of care meters, analyzers and test strips are known throughout the world for their quality, ease of use and outstanding performance.

Covering the testing spectrum from hematology to urinalysis to alcohol testing one can be assured when using a Mission® brand product to expect only accurate results. Ergonomically designed with the end user in mind, the Mission® brand exudes confidence, accuracy, durability and a peace of mind that you would expect from a diagnostic instrument.



Mission® key product features



Small Sample Size – Requires 10µL of capillary or venous blood.



Portable – Handheld meter using AAA batteries or AC adapter.



Sample Type – Capillary or venous whole blood sample.

Hematology



510(k) Cleared
and CLIA Waived

Mission® Plus Hb

SPECIFICATIONS & FEATURES

- 10 µL of capillary or venous whole blood
- Precise results equivalent to automatic hematology analyzers
- Wide Hb measurement range of 5.6 - 23.5 g/dL
- Estimation of hematocrit is only for hemoglobin values from 12.3 to 17.5 g/dL (123 to 175 g/L)
- Small, handheld design for point-of-care / bedside testing
- Devices can be stored at room temperature
- Capillary and venous blood
- Get estimated Hemoglobin (Hb) and Hematocrit (Hct) results in 15 seconds
- Reflectance Photometry



LANCETS 26G

Mission® Lancing Device

SPECIFICATIONS & FEATURES

- The Mission® Lancing Device is designed for use with the Mission® Lancets
- Ergonomically designed for single handed operation
- The Mission® Lancing Device provides improved comfort for easy blood sample collection and has a built-in ejector for safe and easy testing.



CAP TUBES 10µL

Mission® Capillary Transfer Tubes

SPECIFICATIONS & FEATURES

- The Mission® Capillary Transfer Tubes are designed with a single glass capillary tube inside a plastic outer housing and bulb
- Available in a 10µL preset volume, these capillary transfer tubes are ideal for use with the Hemoglobin, Mission® Plus Testing System

Urinalysis

Mission® U120 Smart Urine Analyzer

SPECIFICATIONS & FEATURES

TYPE: Semi-automatic

METHODOLOGY: Reflectance photometry

THROUGHPUT: 60 test/hour in single mode and 120 test/hour in continuous mode

STRIP COMBINATIONS: 14 including microalbumin and creatinine

LOCKOUT FUNCTIONS: Strips, QC and user

MEMORY: 2,000 results

SOFTWARE LANGUAGES: English, French, German, Italian, Portuguese and Spanish



510(k) Cleared and CLIA Waived

Mission® U500 Improved Urine Analyzer

SPECIFICATIONS & FEATURES

TYPE: Semi-automatic

METHODOLOGY: Reflectance photometry

STRIP COMBINATIONS: 15 including microalbumin, creatinine and ascorbic acid.

THROUGHPUT: up 500 tests per hour

LOCKOUT FUNCTIONS: Strips, QC and user

TEST FEATURES: Capture urine color and clarity, set-up a work list to run the samples in a batch

SOFTWARE LANGUAGES: 8 including English, French, German, Italian, Portuguese and Spanish



510(k) Cleared

Mission® Urine Test Strips

SPECIFICATIONS & FEATURES

- Strips combinations with up to 11 parameters
- Parameters available include microalbumin, creatinine and ascorbic acid
- Analytical sensitivity comparable to the market leader
- High quality color chart ensures accurate visual reading
- Over 35 different combinations available 2 year shelf life for unopened canisters



510(k) Cleared and CLIA Waived

Urinalysis

Mission® Microalbumin/Creatinine Urine Test Strips

SPECIFICATIONS & FEATURES

- Detects Albumin as low as 10 mg/L
- Detects Creatinine as low as 10 mg/dL
- 60 seconds for Microalbumin and Creatinine results
- Provides better sensitivity than measuring Protein alone
- Quickly identifies patients who are at risk for developing early kidney disease
- Random testing – no need for a 24-hour urine protein test



510(k) Cleared and CLIA Waived

Mission® Urine Controls

SPECIFICATIONS & FEATURES

- Use with Mission® Urinalysis Reagent Strips and Mission® Urine Analyzers for optimum quality control
- Ensures accurate results for all 11 parameters
- 24 month shelf life at 2 – 8°C
- 2 Packaging Options
 - Dropper bottles
 - Diptubes



510(k) Cleared

Mission® UTI Test Strips

SPECIFICATIONS & FEATURES

- Screens for possible Urinary Tract Infections (UTI)
- Detects Nitrites (NIT) and Leukocyte (LEU) in urine
- 60 seconds for Nitrite results
- 120 seconds for Leukocyte results
- Simple at home test
- Easy to perform and read



510(k) Cleared for OTC

HealthyMe™ UTI Test Strips

SPECIFICATIONS & FEATURES

- Screens for possible Urinary Tract Infections (UTI)
- Detects Nitrites (NIT) and Leukocyte (LEU) in urine
- 60 seconds for Nitrite results
- 120 seconds for Leukocyte results
- Simple at home test
- Easy to perform and read



510(k) Cleared for OTC

Alcohol Testing

Mission® Breath Alcohol Detectors

SPECIFICATIONS & FEATURES

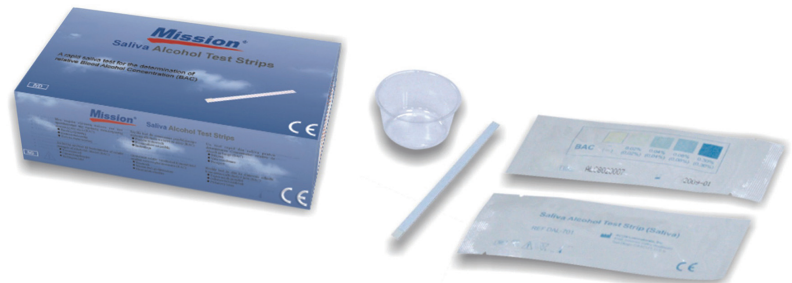
- Results in 2 minutes
- Semi-quantitative
- Available in 0.02%, 0.05% and 0.08%
- Test is easy to perform and interpret
- 3 year shelf life at room temperature



Mission® Saliva Alcohol Test Strips

SPECIFICATIONS & FEATURES

- Results in 2 minutes
- Enzymatic Reaction
- Single strip detects concentrations of 0.02 – 0.30% BAC
- Test is easy to perform and interpret
- 18 month shelf life at room temperature



Veterinary Diagnostics



CentriVet® Glucose/Ketone Meter

SPECIFICATIONS & FEATURES

- Sample Size: Glucose 0.8 μ L, β -Ketone 1.2 μ L
- Test Range β -Ketone: 0 – 8.0 mmol/L
- 20-60% Hematocrit Range for both Glucose and β -Ketone
- 450 test memory
- Calibrated specifically for Bovine, Canine, and Feline testing

Veterinary Products

Designed for our Animal Companions

Bovine

Canine

Feline



CentriVet® Urine Reagent Test Strips

SPECIFICATIONS & FEATURES

TEST PARAMETERS: LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU

- 60 seconds to results for most parameters
- Clinically proven accuracy
- Available in 100 strips per canister
- 90 days use life in opened canister

Notes

Notes

ACON works strategically with its sister companies to produce high quality medical products that meet and exceed the customers exact quality expectations.

We are committed to continuously monitoring our quality systems to ensure their effectiveness and compliance to all applicable regulatory and quality requirements. Exceeding customer expectations and maintaining customer loyalty are our top priorities

ACON LABORATORIES, INC.

YourTrustedPartner



ACON Laboratories, Inc.
San Diego, CA 92121, U.S.A.
Telephone: 1.800.838.9502
Fax: 1.858.200.0729
Email: info@aconlabs.com
aconlabs.com