ScoutPro

Osmolarity System

Tear Osmolarity Testing
RESOURCE GUIDE

Trukera MEDICAL

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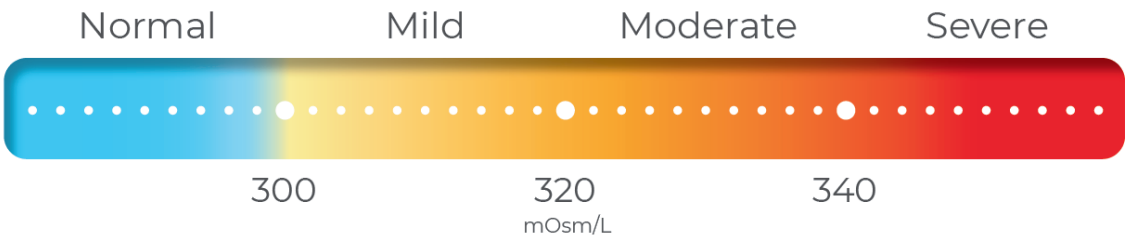
Trukera™ OSMOLARITY SCALE



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The Impact of Unhealthy Tear Film on Your Vision

STABLE

A healthy tear film and ocular surface provides clear, stable vision.

UNSTABLE/FLUCTUATING

An unhealthy tear film and ocular surface can lead to unstable, fluctuating vision from blink to blink.

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Testing Procedure

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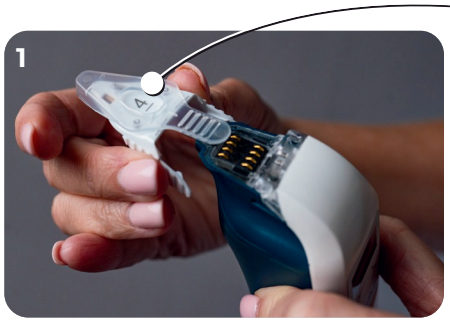
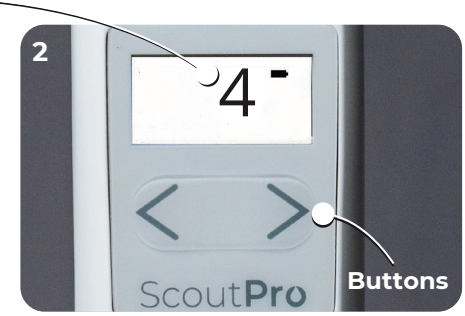
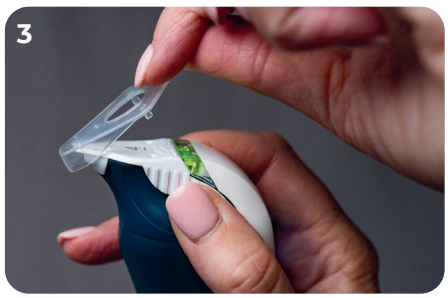
Osmolarity System

Use good hygiene when collecting tears. Throw away used Test Cards in an appropriate container.





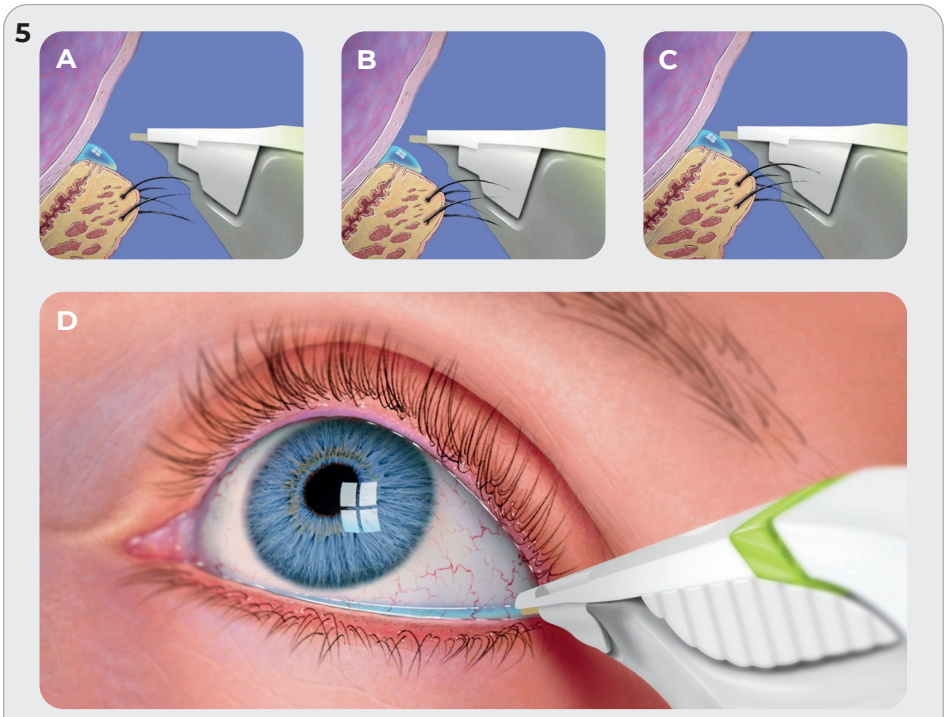
Attach Test Card. Enter the code on the top of the card by pressing right (>) or left (<) buttons on the Pen.



Hold wings, remove cover.

Seat patient with head back and eyes looking up and towards ceiling.

- **Do NOT pull the eyelid away from the eye.**
- When tears are collected, the Pen will beep.



Lower Pen until the bottom of the tip touches the line of moisture on top of the eyelid. Keep the Pen in contact with the eyelid, lightly brush the Pen back and forth, **do NOT peck.**"

A test result will appear on the display. DO NOT DOCK the Pen while waiting for results. Record the test result in the patient's chart.

Remove the test card by sliding forward with your index finger and discard. Do NOT reuse Test Cards.

To view previous test results, press either the right (>) or left (<) buttons on the Pen.

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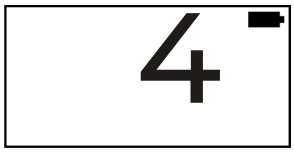
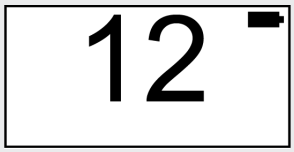
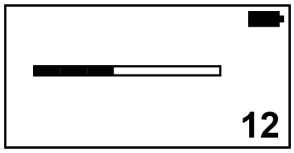
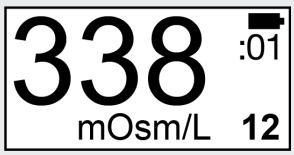
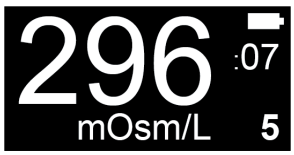
Display Screen Explanation

ScoutPro
Osmolarity System

THE DISPLAY	YOU WILL SEE THIS WHEN...	EXPLANATION
	**A new Test Card is inserted**	The Test Card code for the previous test is shown in the center of the display. The battery icon showing the charge of the Pen is in the upper right-hand corner of the display.
	**A new Test Card code is entered**	Before testing a patient, press the right (>) or left (<) buttons on the Pen until the number on the display matches the code printed on top of the new Test Card.
	**A tear sample has been collected**	When a tear sample has been collected, a progress bar will be shown on the display while the sample is analyzed. The numeric code for this test is shown in bold in the lower right corner.
	**The test is complete**	The current test result will be displayed in black text on a white background. Removing the Test Card will push this result into memory and turn the screen off. The numeric code for the test is shown in bold in the lower right corner.
	**A previous test result is recalled**	Previous test results will be displayed in white text on a black background, and include the previous result (296), the code used for that test (5), and the minutes elapsed since it was performed (e.g., :07).

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Frequently Asked Questions

ScoutPro™
Osmolarity System

1. WHAT IS A NUMERIC CODE?

There is a numeric code printed on the top of each Test Card. The code needs to match the number on the Pen display for the test to be accurate. Within 5 seconds of a new Test Card being placed onto the Pen, immediately change the code on the Pen (using the < and > buttons) to match the numeric code on the Test Card.

2. WHAT DOES IT MEAN IF THE GREEN LIGHT ON THE PEN DOES NOT TURN ON?

If the green light does not turn on, then do NOT test a patient. The green light tells you the Pen is ready for you to perform a test.

3. HOW DO I KNOW IF I HAVE SUCCESSFULLY COLLECTED A TEAR SAMPLE?

The green light will turn off and the pen will beep.

4. HOW CAN I DETERMINE IF A TEST CARD HAS BEEN USED?

A Test Card without a protective cover should always be considered a used Test Card. All Test Cards should be discarded after use. Do NOT reuse Test Cards.

5. WHAT IS PROPER HYGIENE FOR TESTING?

Always disinfect your hands and keep the ScoutPro Pen clean. Read the Osmolarity Test Card insert for more information.

6. HOW OFTEN SHOULD I TEST THE BLUE ELECTRONIC CHECK CARD?

Test the blue Electronic Check Card once a day before testing a patient or if a Pen has been dropped or mishandled.

7. HOW OFTEN SHOULD I TEST THE CONTROL SOLUTIONS?

Test both levels of Control Solution with each new shipment of Test Cards (even if the lot number is the same as the previous shipment), with each new lot of Test Cards, and monthly to check storage.

8. HOW SHOULD I STORE THE TEST CARDS?

Test Cards should be stored at room temperature. Pay attention to the expiration date printed on the box and on each package. Never use a Test Card after the expiration date.

9. WHAT IF THE QUALITY CONTROL TESTING FAILS?

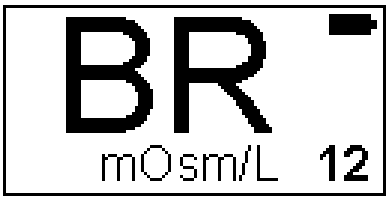
Stop testing. Contact Trukera technical support in your area or call Trukera at (858) 455-6006. Refer to the User Manual for information on troubleshooting and maintenance.

10. HOW CAN I RESET THE PEN IF NECESSARY?

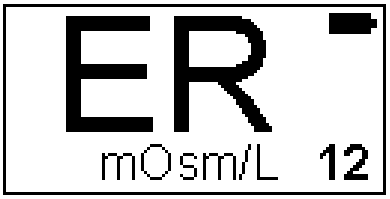
Unscrew the battery cover on the back of the Pen and remove the batteries. Reinsert the batteries, replace the cover and screw into place.

Error Codes

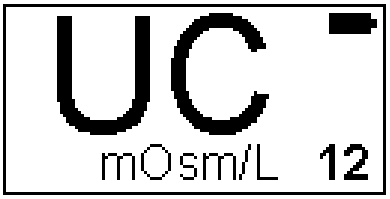
AR: Above Range
Above range means the test is over 400 mOsm/L. Although that is feasible, it is rare.



BR: Below Range
Below range error is typically the result of a testing technique error due to “pecking” or contacting the patient’s lid margin and then pulling away. This causes air to clog the channel the tear needs to travel down inside the test card. Always keep test card in contact with the lid margin during the test.



ER: Device Error
ER signifies a general device error that is typically cleared by resetting the ScoutPro Pen.



UC: Used Card
UC indicates that the test card attached to the ScoutPro Pen has already used to collect a tear sample.

LO: Low Battery
LO indicates a low battery reading and the need to recharge/replace the AAA batteries in the ScoutPro Pen.

Proper Battery Replacement

ScoutPro Osmolarity System

Important Note!
Only *rechargeable* AAA batteries should be used in the ScoutPro Pen. Use of non-rechargeable batteries may damage the Pen and void the warranty.

Recommended Batteries

DURACELL AAA 900 mAh Nickel Metal Hydride Battery

Electrical Characteristics

Rated Capacity (ANSI C18.2M, Part 1)	900 mAh
Nominal Voltage (at +20˚C)	1.2 V
Operating Voltage	1.0 V - 1.35 V
Typical Impedance @ 1 kHz	35 Ohm

Key Features

- High voltage response, stable during most of the lifetime of the application
- Reliable performance
- Wide operating temperature range (-10˚C / +50˚C)
- Excellent resistance to corrosion
- Designed to meet all major quality, safety and environment standards:
  - Safety: IEC 62133-1 & ANSI C18.2: Part 2
  - RoHS and REACH compliance
  - Quality: ISO 9001, Duracell World Class Continuous Program

Congratulations.

Your ScoutPro Osmolarity System is almost ready to be used. The ScoutPro Osmolarity System, categorized under the Clinical Laboratory Improvement Amendments (CLIA) as waived, is fully automated and not operator dependent. However, there are certain requirements to ensure that your device continues to operate at peak efficiency.

This binder will provide instructions and the data sheets necessary to log your quality test results, in accordance with CLIA requirements. Use these sheets as the Master to log your information. Please make copies of the Daily QC, Monthly QC and Received Test Cards QC logs and follow the instructions below.

The Blue Electronic Check Card should be used to test the ScoutPro Pen before each day of patient testing. The Blue Electronic Check Card is used to confirm the function and calibration of the ScoutPro Osmolarity System. Record all results on the Daily Quality Control Log.

Good laboratory practice requires the use of Normal and High Osmolarity Control Solutions to ensure that the Test Cards are functioning properly. Normal and High Osmolarity Control Solutions should be tested once per month, with each lot number of Test Cards, or when a new shipment is received, even if it is of the same lot number as that of Test Cards received previously. Record all test results on either the Monthly Quality Control Log or the Received Test Cards Quality Control Log.

If you have any questions regarding this binder, please contact Trukera Medical.

Tel: (855) 832-7522 or (858) 455-6006
42309 Winchester Road, Suite I
Temecula, CA 92590

Quality Control Testing

ScoutPro Osmolarity System

When testing the control solution or the Electronic Check Cards, make sure the results match the expected values shown in the instruction sheets. If they do not match, the quality tests have FAILED. Stop testing. Contact Trukera Customer Support in your area or call Trukera at **(858) 455-6006.**

Electronic Check Card

Read the Electronic Check Card instruction sheet for expected values. Be sure to test the blue Electronic Check Cards on the Pen once a day before patient testing. Do NOT collect tears or control solutions with the Electronic Check Cards.

Procedure

- Attach Electronic Check Card onto the Pen.
- The Pen will beep and a green light will turn on.
- A test result will appear on the display.
- If results FAIL, stop testing. Contact Trukera Customer Support in your area or call Trukera at **(858) 455-6006**.

Control Solutions

Test both levels of Control Solutions with each new shipment of Test Cards (even if the lot number is the same), with each new lot number, and monthly to check storage. Read the Control Solution instructions sheet for expected values.

Procedure

- Allow Test Cards and Control Solution to equilibrate at room temperature in the testing room for 30-minutes prior to testing.
- Attach a Test Card to the Pen (refer to this guide), enter the code.
- Do NOT collect tears.
- Instead of collecting tears, use a Control Solution.
- Use the blue sleeve to snap off the top of an ampule.
- Turn the ampule upside down (the fluid will not spill out).
- Touch the tip of the Pen to the Control Solution.
- Compare Control Solution results to the expected value.
- If test results are within the expected range, patient testing may proceed.
- If test results are not within the expected range, you should not perform patient testing. Contact Trukera Customer Support in your area or call Trukera at **(858) 455-6006.**

SERIOUS ADVERSE EVENT

Report a serious adverse event, product quality problem, product use error, or therapeutic inequivalence /failure that you suspect is associated with the use of the ScoutPro Osmolarity System to Trukera Customer Support (Tel: (858) 455-6006) and/or to FDA MedWatch (Tel: (800) FDA-1088, Fax: (800) FDA-0178, or www.fda.gov/medwatch).

For outside the US, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

OPERATOR TRAINING LOG
CLIA WAIVER

ScoutPro
Osmolarity System

Clinic Name: _____

Trainee Name	Trainer Name	Completed Training Date

ScoutPro operators are to be competent in all of the following:

Set Up
- AAA rechargeable batteries installed in ScoutPro Pen
- Charger Base plugged into electrical outlet
- ScoutPro Pen docked in Charger Base and battery icon displayed

Tear Collection
- Proper insertion of Test Card onto Pen
- Proper removal of Test Card cover
- Input of numeric Test Card code into Pen
- Successful collection of tear sample
- Obtain test results and previous test results in memory
- Removal of Test Card from Pen and disposal

Quality Control - Electronic Check Card
- ECC Testing
- Daily QC Log

Quality Control - Control Solutions
- Control Solution Testing - Normal and High Control Solutions
- Completion of Monthly and Received Test Card Shipment QC Logs

QUALITY CONTROL LOG
CLIA WAIVER
DAILY

ScoutPro
Osmolarity System

Use the blue Electronic Check Cards (ECC) each day of patient testing to test the ScoutPro Osmolarity System. Record the results in the table below. Follow instructions in the Trukera Medical Quick Reference Guide. Call Trukera at (858) 455-6006 if testing fails.

ScoutPro Serial Number	Electronic Check Card (ECC) Expected Range	Optimal Room Temperature*
	331 - 337 mOsm/L	20° - 25 C 68° - 77 F

Date	Operator ID	ECC Record Test Result	Date	Operator ID	ECC Record Test Result
3/11/2024	KAP	334 mOsm/L ☑ Pass ☐ Fail			____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail			____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail			____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail			____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail			____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail			____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail			____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail			____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail			____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail			____ mOsm/L ☐ Pass ☐ Fail

***FDA Labeling**	Room Temperature
Allowed	15 - 30°C, 59 - 86°F
Transport and Storage	Controlled Room 20 - 25°C, 68 - 77°F
	Excursions Permitted to 15 - 30°C, 59 - 86°F

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QUALITY CONTROL LOG
CLIA WAIVER
MONTHLY

ScoutPro
Osmolarity System

Normal and High Osmolarity Control Solutions are to be tested on each ScoutPro Osmolarity System once per month. Record test results below. Follow instructions in the ScoutPro Quick Reference Guide. Call Trukera Medical at (858) 455-6006 if testing falls outside of range.

ScoutPro Serial Number	Normal Control Solution Lot # and Expiration Date	High Control Solution Lot # and Expiration Date

Electronic Check Card (ECC) Expected Range	Normal Control Solution* Optimal Range	High Control Solution* Optimal Range
331 - 337 mOsm/L	288 - 305 mOsm/L	330 - 346 mOsm/L

Date	Operator ID	Electronic Check Card	Test Card Lot No. & Expiration Date	Normal Control Solution	High Control Solution
3/11/2024	KAP	334 mOsm/L ☑ Pass ☐ Fail	00001630 Sep 2026	300 mOsm/L ☑ Pass ☐ Fail	341 mOsm/L ☑ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail		____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail		____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail		____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail		____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail		____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail		____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail		____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail		____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
		____ mOsm/L ☐ Pass ☐ Fail		____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail

*FDA Labeling	Expected	Ranges
Normal Control Solution	297 mOsm/L	282 - 312 mOsm/L
High Control Solution	338 mOsm/L	323 - 353 mOsm/L

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QUALITY CONTROL LOG
CLIA WAIVER
TEST CARDS RECEIVED

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Osmolarity System

Normal and High Osmolarity Control Solutions are to be tested with each new lot number of Test Cards or when a new shipment of Test Cards is received, even if it is the same lot number as Test Cards received previously. Follow instructions in the ScoutPro Quick Reference Guide. Call Trukera Medical at (858) 455-6006 if testing falls outside of range.

Electronic Check Card (ECC) Expected Range	Normal Control Solution* Optimal Range	High Control Solution* Optimal Range
331 - 337 mOsm/L	288 - 305 mOsm/L	330 - 346 mOsm/L

Date	Operator ID	ScoutPro Serial Number	Test Card Lot No. & Expiration Date	Normal Control Solution	High Control Solution
3/11/2024	KAP	0110060001238	00001630 Sep 2026	300 mOsm/L ☑ Pass ☐ Fail	341 mOsm/L ☑ Pass ☐ Fail
				____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
				____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
				____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
				____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
				____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
				____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
				____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
				____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail
				____ mOsm/L ☐ Pass ☐ Fail	____ mOsm/L ☐ Pass ☐ Fail

*FDA Labeling	Expected	Ranges
Normal Control Solution	297 mOsm/L	282 - 312 mOsm/L
High Control Solution	338 mOsm/L	323 - 353 mOsm/L

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ERROR LOG
CLIA WAIVER

ScoutPro
Osmolarity System

Please record any error code (ER or BR) displayed by the ScoutPro when performing a patient or quality control test. Repeat the test with a new Test Card, and if the error persists, contact Trukera Medical Technical Support at (855) 832-7522 x1 or technicalsupport@trukera.com.

Test cards recorded on the Error Log will be replaced free of charge 40 at a time.

No.	Date	Error Code	Pen Serial No. (last 4 digits)	Operator ID
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

No.	Date	Error Code	Pen Serial No. (last 4 digits)	Operator ID
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				
32				
33				
34				
35				
36				
37				
38				
39				
40				

Practice Name	
Customer Signature	
Customer Printed Name	
Date Submitted	

FOR INTERNAL USE ONLY

Rep Name _____

Rep Signature _____

Date Processed _____

Trukera MEDICAL

Billing and Reimbursement

This guide addresses billing recommendations for CPT® 83861, "Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity", a covered service by CMS Medicare under the Clinical Laboratory Fee Schedule. CLIA Certification is required to perform and bill laboratory tests.

Billing Codes and Modifiers

CMS Medicare Part B: $22.48 per test ($44.96 per patient)

- No deductible or patient co-payment applies
- Code CPT 83861 as one unit of service with QW modifiers followed by LT/RT on two lines, once for each eye:

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Trukera Medical | 17a. | 17b. NPI 1234567890

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES: FROM MM DD YY TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? ☐ YES ☒ NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.
A. ICD-10 Code (s) B. C. D.
E. F. G. H.
I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER: 10D2345678

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER			E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
09	01	22	09	01	22	11		83861	QW	RT		A	40 00	1		NPI	1234567890
09	01	22	09	01	22	11		83861	QW	LT		A	40 00	1		NPI	1234567890

Commercial Third Party, Medicare Advantage Part C and Medicaid

Reimbursement, coding and coverage policies will vary by carrier, provider contract, and patient benefit plan. Contact the Trukera Medical Reimbursement Support Specialist for details on specific payers and billing guidance.

Diagnostic Codes

Medical necessity rules are met when a patient presents with a sign or symptom of dry eye as determined by the clinician, which should be documented in the patient's medical record. Codes commonly used for coding dry eye diagnosis and/or dry eye symptoms, as referenced in the clinical literature, are available on the "ICD-10 Coding for Dry Eye" brochure.

Currently CMS has no National Coverage Determinations (NCD) that define diagnosis codes to bill for CPT 83861 tear osmolarity test, so a decision to perform a test based on signs or symptoms of dry eye is up to the physician. Always ensure that all the items listed below in "Documenting a Laboratory Test" are included in the patient record to meet medical necessity guidelines.

Documenting a Laboratory Test

Medicare has several documentation requirements for laboratory tests such as tear osmolarity, which must be noted in the patient chart or Electronic Health Record (EHR).

1. The sign or symptom of disease that prompted the ordering of the test
2. A notation in the medical record that a "tear osmolarity test was ordered" with "tear osmolarity" specifically identified
3. The numerical tear osmolarity test results and indication if the results were normal or abnormal
4. Treatment/Management Plan—the medical action taken as a result of the tear osmolarity test, and referencing the test results in the plan
5. Managing clinician's signature at the end of the record indicating that everything in the record that day was reviewed and confirmed as medically necessary

Note that Medicare and most commercial payers do not cover screening tests, thus a sign or symptom of dry eye, or a previously diagnosed but “unstable” dry eye under management, must be properly documented prior to submitting a claim for reimbursement for a tear osmolarity test.

What if the tear osmolarity test is normal?

If the tear osmolarity test result is normal and dry eye is “ruled out”, code for the final or confirmed diagnosis, and “the symptoms that prompted ordering the test may also be reported as additional diagnosis if they are not fully explained or related to the confirmed diagnosis.” (ref: CMS Program Memorandum AB-01-144, Sept 26, 2001) CMS coverage rules for laboratory tests state, “The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. In these cases, the sign or symptom should be used to explain the reason for the test.” (ref: Fed Reg Vol 66, No 226, Nov 23, 2001)

How often can I perform a tear osmolarity test?

Medical necessity as determined by the clinician determines how often a tear osmolarity test may be performed and must accompany proper documentation consisting of either a current sign or symptom of disease, or a patient under therapy that is being managed for a previously diagnosed but “unstable” dry eye. Testing a patient with a prior history of dry eye without current signs or symptoms of disease would likely be considered a “screening” test.
All items noted in “Documenting a Laboratory Test” must be included in the patient medical record to ensure proper support for multiple testing.

Are there global period exclusions?

No, laboratory tests do not apply to “global period” exclusions for procedures such as the 10-day global period for punctal occlusion and 90-day post-operative global exclusion for cataract surgery. (ref: Medicare Claims Processing Manual Chapter 12, Section 40.1)

Trukera Medical requests that the office billing department NOT spend time to resolve billing issues for CPT 83861, and instead contact the Trukera Medical Reimbursement Support Center, under a Business Associate Agreement. A Reimbursement Support Specialist will review the problem and recommend a resolution, including direct interaction with the payer if necessary.

Email us at rsc@trukera.com

Trukera™ MEDICAL

Trukera MEDICAL | 5 STEPS TO DOCUMENT A LABORATORY TEST

Medicare has several documentation requirements for point-of-care laboratory tests such as tear osmolarity, which must be noted in the patient chart or Electronic Health Record (EHR). Together with your Trukera Medical representative, please review your EHR or paper Intake Form to ensure that all 5 points described here are being captured correctly.

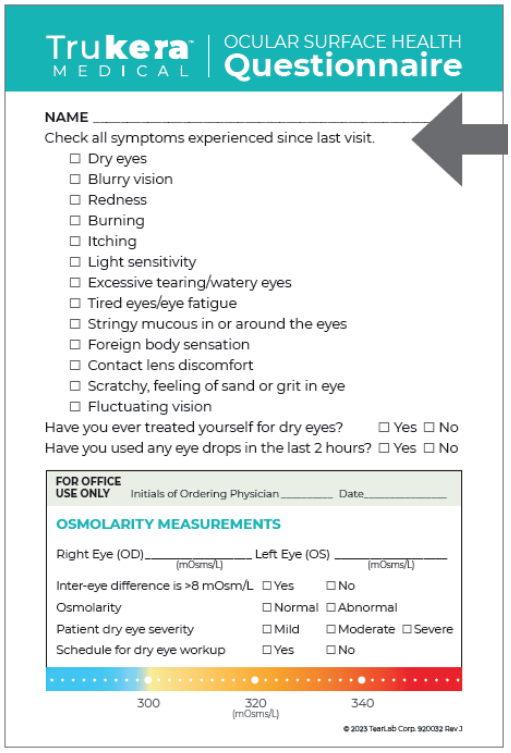
REMEMBER, IN AN AUDIT, IF IT IS NOT DOCUMENTED PROPERLY AND LEGIBLY, IT DID NOT HAPPEN.

1 Note the sign or symptom of disease that prompted the ordering of the test.

You may use one of the standard dry eye questionnaires (DEQ-5, OSDI, or SPEED), design your own questionnaire, or utilize the Ocular Surface Health Questionnaire provided by Trukera Medical. Dry eye signs or symptoms must be noted in the patient's record for that day. Ideally, the symptom questionnaire can be added to or scanned into the EHR as further documentation. Signs or symptoms must be current complaints and not from a prior patient visit or history. A return visit to monitor therapy for an "unstable condition" would be sufficient to justify a test, but that must also be documented in the chart, and the condition that is being monitored must be indicated as still active and/or unstable.

Osmolarity testing may be performed any time during the office visit if medical documentation exists showing the doctor had the intent for the test to be performed, and that intent has been authenticated by the doctor via a handwritten or electronic signature in the chart.
See rules in 42 CFR 410 and Pub. 100-02 Chapter 15, §80.6.1.

A prior history of dry eye is not sufficient to justify a test. The patient must present with current signs or symptoms of disease, an unstable condition, or a return for the monitoring of therapy, all of which must be properly documented.


Trukera MEDICAL | OCULAR SURFACE HEALTH Questionnaire

NAME _____

Check all symptoms experienced since last visit.

- ☐ Dry eyes
- ☐ Blurry vision
- ☐ Redness
- ☐ Burning
- ☐ Itching
- ☐ Light sensitivity
- ☐ Excessive tearing/watery eyes
- ☐ Tired eyes/eye fatigue
- ☐ Stringy mucous in or around the eyes
- ☐ Foreign body sensation
- ☐ Contact lens discomfort
- ☐ Scratchy, feeling of sand or grit in eye
- ☐ Fluctuating vision

Have you ever treated yourself for dry eyes? ☐ Yes ☐ No
Have you used any eye drops in the last 2 hours? ☐ Yes ☐ No

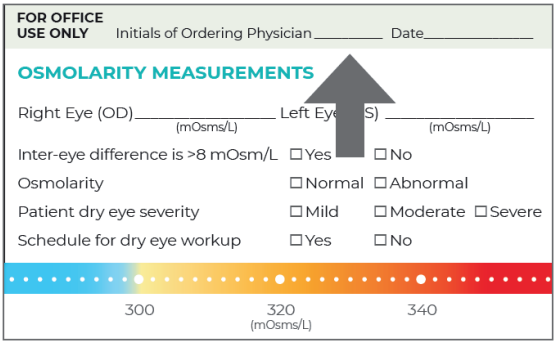
FOR OFFICE USE ONLY Initials of Ordering Physician _____ Date _____

OSMOLARITY MEASUREMENTS

Right Eye (OD) _____ (mOsms/L) Left Eye (OS) _____ (mOsms/L)
Inter-eye difference is >8 mOsm/L ☐ Yes ☐ No
Osmolarity ☐ Normal ☐ Abnormal
Patient dry eye severity ☐ Mild ☐ Moderate ☐ Severe
Schedule for dry eye workup ☐ Yes ☐ No

300 320 (mOsms/L) 340

2 Specifically identify the test in the medical record by stating "tear osmolarity test was ordered."


FOR OFFICE USE ONLY Initials of Ordering Physician _____ Date _____

OSMOLARITY MEASUREMENTS

Right Eye (OD) _____ (mOsms/L) Left Eye (OS) _____ (mOsms/L)
Inter-eye difference is >8 mOsm/L ☐ Yes ☐ No
Osmolarity ☐ Normal ☐ Abnormal
Patient dry eye severity ☐ Mild ☐ Moderate ☐ Severe
Schedule for dry eye workup ☐ Yes ☐ No

300 320 (mOsms/L) 340

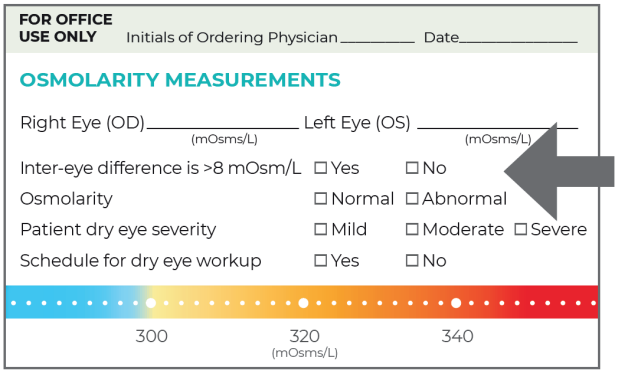
Document the name of the test (i.e., tear osmolarity); do not use acronyms (i.e., TOT). Although an order for a laboratory test is always required, Medicare regulations allow an order for an in-office laboratory test to be verbal and unsigned, as long as there is "medical documentation (e.g., progress note) by the treating physician that he/she intended the clinical diagnostic test to be performed. This documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature." [1] (see point #5)

Payers will not pay for the test if it is not used to manage the patient and identified by name (i.e., tear osmolarity) in the progress notes. Do not use abbreviations, (e.g., TOT).

1. Medicare Program Integrity Manual. CMS Publlcatlon 100-08, Chapter 3; para. 3.3.2.4 Exception 2.

3 Record the numerical tear osmolarity test results and indicate if the results were “normal” or “abnormal.”

It is not sufficient to just document the test results. You need to show that someone reviewed the test results to determine if they were “normal” or “abnormal,” as per published reference values or your dry eye protocol. You must indicate that the laboratory test was used to manage the patient during that visit. Determining if the test results were normal or abnormal is critical documentation. This can be a simple check box in the chart or a comment in the progress notes.



Return visits for therapeutic monitoring must have previous test results documented for comparison to current test results and support a change in the status of the patient’s condition.

4 Determine the Treatment/Management Plan (i.e., the medical action taken as a result of the tear osmolarity test) and reference the test results in the plan.

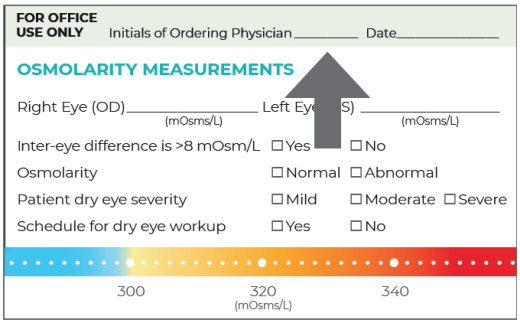
This is important, as payers will not pay for a test unless it is used to manage the patient, as indicated in point #3. Even if the test results are “normal” that should be indicated in the progress notes, because it has direct impact on the final diagnosis or Management Plan.

Laboratory tests will be covered if results are either “Normal” or “Abnormal.” Either result must be used in the management of the patient (e.g., “Tear Osmolarity ‘Normal’, Dry Eye no longer considered, Dx Ocular Allergy”).

Be sure that osmolarity testing is noted for the next follow-up appointment if it is part of the management plan. This can be referenced for the day of the test:

> *“Patient returning per doctor directed orders for evaluation of the tear film, osmolarity findings, and retinal macular evaluation secondary to ocular surface disease noted at the last visit 3 months ago.”*

5 Ensure the clinician signed the record indicating that everything in the chart that day was reviewed and confirmed as medically necessary.



As discussed in point #2, a verbal order is not unusual for an in-office laboratory test, and the clinician’s signature in the chart indicates the doctor’s *“intent that the clinical diagnostic test be performed.”* If you are using a paper symptom questionnaire, the doctor's initials on the questionnaire provide additional documentation that the symptoms leading to the ordering of the test were properly reviewed.

The codes provided below are commonly used for coding dry eye diagnoses and/or dry eye symptoms. **This information is not intended to be used as an inclusive nor restrictive list of codes associated with, or reimbursed for osmolarity testing.**

Diagnosis – Dry Eye Disease with Hyperosmolarity	ICD-10[1,2]
Keratoconjunctivitis sicca, non-Sjögren's syndrome, right eye	H16.221
Keratoconjunctivitis sicca, non-Sjögren's syndrome, left eye	H16.222
Keratoconjunctivitis sicca, non-Sjögren's syndrome, bilateral	H16.223
Conjunctival xerosis, right eye	H11.141
Conjunctival xerosis, left eye	H11.142
Conjunctival xerosis, bilateral	H11.143
Dry eye syndrome of right lacrimal gland	H04.121
Dry eye syndrome of left lacrimal gland	H04.122
Dry eye syndrome of bilateral lacrimal glands	H04.123
Exposure keratoconjunctivitis, right eye	H16.211
Exposure keratoconjunctivitis, left eye	H16.212
Exposure keratoconjunctivitis, bilateral	H16.213
Sicca syndrome (Sjögren) with keratoconjunctivitis	M35.01
Sicca syndrome (Sjögren), unspecified	M35.00
Superficial keratitis, unspecified, right eye	H16.101
Superficial keratitis, unspecified, left eye	H16.102
Superficial keratitis, unspecified, bilateral	H16.103
Filamentary keratitis, right eye	H16.121
Filamentary keratitis, left eye	H16.122
Filamentary keratitis, bilateral	H16.123
Punctate keratitis, right eye	H16.141
Punctate keratitis, left eye	H16.142
Punctate keratitis, bilateral	H16.143
Neurotrophic keratoconjunctivitis, right eye	H16.231
Neurotrophic keratoconjunctivitis, left eye	H16.232
Neurotrophic keratoconjunctivitis, bilateral	H16.233
Recurrent erosion of cornea, right eye	H18.831
Recurrent erosion of cornea, left eye	H18.832
Recurrent erosion of cornea, bilateral	H18.833

1. 2007 Report of the International Dry Eye Workshop (DEWS). The epidemiology of dry eye disease. *The Ocular Surface.* 2007;5(2):96. **2.** Hovanesian JA, et al. Symptoms of dry eye and recurrent erosion syndrome after refractive surgery. *J Cataract Refract Surg*. 2001 Apr;27(4):577-84.

The codes provided below are commonly used for coding dry eye diagnoses and/or dry eye symptoms. **This information is not intended to be used as an inclusive nor restrictive list of codes associated with, or reimbursed for osmolarity testing.**

DIAGNOSIS • Dry Eye Symptoms, normal osmolarity • Undiagnosed Dry Eye with Symptoms	**ICD-10**[1,2]	**OSDI** *Symptoms*[3]	**SPEED** *Symptoms*[4]	**DEQ-5** *Symptoms*[5]
Visual discomfort, right eye	H53.141	1. Eyes that are sensitive to light	Eye fatigue	Eye discomfort
Visual discomfort, left eye	H53.142			
Visual discomfort, bilateral	H53.143			
Ocular pain, right eye	H57.11	2. Eyes that feel gritty 3. Painful or sore eyes	Dryness, grittiness or scratchiness Soreness or irritation Burning	Eye discomfort Eye dryness
Ocular pain, left eye	H57.12			
Ocular pain, bilateral	H57.13			
Epiphora, right lacrimal gland	H04.201		Watering	Watery eyes
Epiphora, left lacrimal gland	H04.202			
Epiphora, bilateral lacrimal gland	H04.203			
Other visual disturbances Description synonyms • Blurred vision • Hazy vision • Multiple visual images • Reduced visual acuity • Visual acuity reduced • Visual disturbance, multiple images	H53.8	4. Blurred vision 5. Poor vision		

Trukera Medical provides this information for illustrative purposes only. Providers should follow coding conventions for diagnostic tests as well as payer instructions when selecting appropriate ICD-10-CM diagnosis codes. These are diagnostic codes that are commonly used for dry eye diagnosis or dry eye symptoms as identified in the clinical literature. See Medicare Claims Processing Manual (Pub 100-04, Chapter 23, Section 10.1). Use of codes provided herein does not guarantee payment.

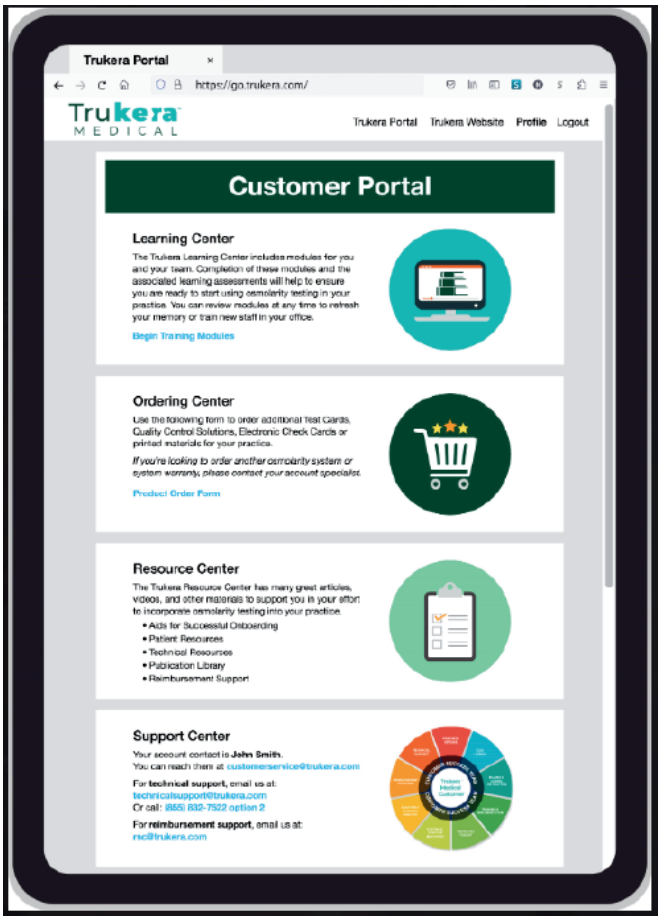
3. Schiffman RM, et al. Reliability and Validity of the Ocular Surface Disease Index. *Arch Ophthalmol*. 2000;118(5):615-621. **4**. Ngo W, et al. Psychometric Properties and Validation of the Standard Patient Evaluation of Eye Dryness Questionnaire. *Cornea*. 2013;32:1204–1210. **5**. Chalmers RL, et al. Validation of the 5-Item Dry Eye Questionnaire (DEQ-5): Discrimination across self-assessed severity and aqueous tear deficient dry eye diagnoses. *Contact Lens & Anterior Eye*. 2010;33(2):55-60.

Trukera Medical Customer Portal

Customer Portal

ScoutPro Osmolarity System

Through our self-service Customer Portal, we have now made it more convenient than ever to order testing supplies, find useful resources, access on-demand training, and contact us for support. We hope this new portal will be a great addition to the personal support you receive from our team.



LEARNING CENTER

Access on-demand training videos to learn more about tear osmolarity and testing

RESOURCE CENTER

A library of our most-valuable customer resources is available, organized by categories, and archived in a searchable database

ORDERING CENTER

The process for online ordering of printed materials, test cards and quality control solutions has been streamlined into a simple format for your convenience

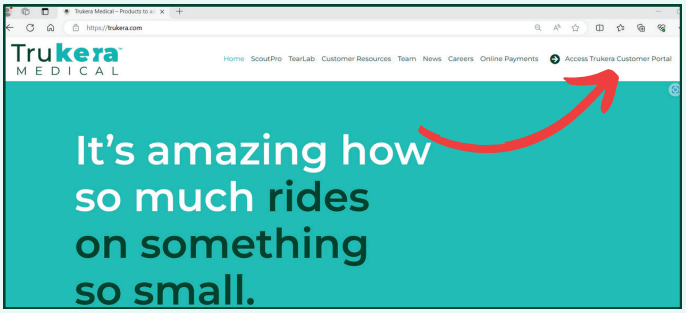
SUPPORT CENTER

Contact information is in a centralized location so you can reach the right Trukera team member for your needs

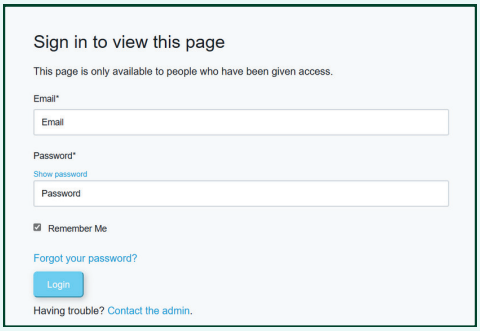
Scan the QR code below to visit Trukera.com and navigate to the Customer Portal

HOW TO USE THE ORDERING CENTER

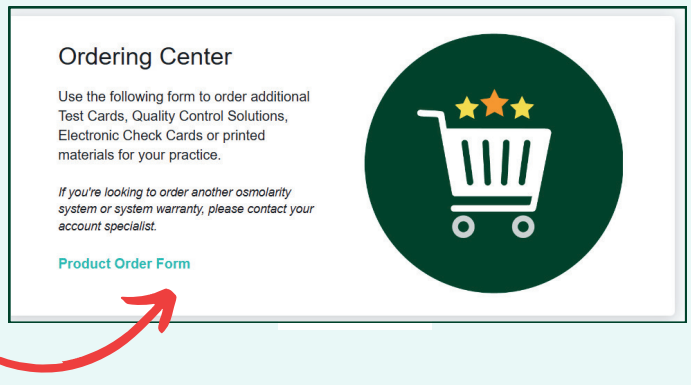
1 Go to Trukera.com
Click “Access Trukera Customer Portal”



2 Login with your email and password.

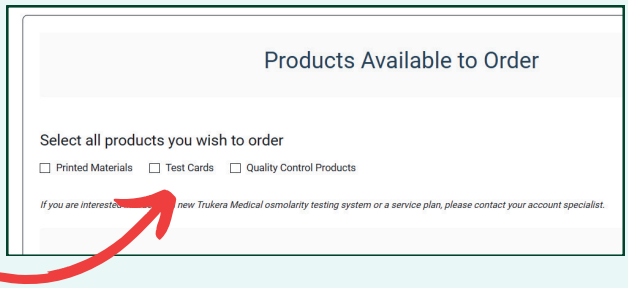


3 Click “Ordering Center” from the left side menu or scroll down the page to find the Ordering Center section.
Click “Product Order Form”



4 Check the boxes of the product types you would like to order:

- Printed Materials,
- Test Cards, or
- Quality Control Products.



- Select the desired quantities of each item
- Confirm/complete shipping information
- Click “Complete Order” to submit

Trukera™
MEDICAL

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