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INTENDED USE
FructoScreen® is a photometric method used for detecting fructose in seminal plasma. The results obtained should be considered as provisional and should not be used in isolation but together with all the information available.

SUMMARY
This photometric method measures the amount of fructose in seminal plasma. In the first step, all proteins as well as particulates are separated from the seminal plasma which contains fructose. In the second step, the deproteinized seminal plasma is incubated with indole. The indole changes to a yellow-orange color in the presence of fructose. The intensity of this color can be measured in a microplate reader and is directly related to the amount of fructose in the seminal plasma. Using a formula, both the concentration of fructose and the total amount of fructose present can be calculated.

PRECAUTIONS
All semen samples should be considered potentially infectious. Handle all specimens as if capable of transmitting HIV and hepatitis. Specimens should be disposed of in accordance with OSHA guidelines.
Avoid inhaling the Concentrated Hydrochloric Acid while performing the test. Avoid skin contact with the Concentrated Hydrochloric Acid. In the event that the acid gets on your skin or in your eyes, flush with copious amounts of water for at least 15 minutes.

STABILITY AND STORAGE
FructoScreen is stable to the stated expiration date when stored at the required temperatures. Store the Indole below 0º C and thaw fully before using. Store the other components at room temperature.

USER QUALITY CONTROL
Any product showing cloudiness, turbidity, precipitation, or coloration should be discarded. It is recommended to run positive and negative controls for each test.

SPECIMEN COLLECTION AND PREPARATION
Semen should be collected in a clean cup and stored at room temperature until use. Semen can also be stored frozen by placing specimen in an ordinary freezer until assaying at a later time. No special procedures are needed for freezing and thawing.

PROCEDURE
Materials Provided with FructoScreen (#0006040): Solution A, Solution B, Indole, Fructose Standard, Empty Dropper Bottle for concentrated hydrochloric acid, 96-well plate with lid.

Materials Not Provided: Concentrated hydrochloric acid, Test tubes and rack, Pipettors and tips, Distilled or deionized water, Collecting cups, Centrifuge, capable of 1500xg, Air incubator, Microplate reader capable of reading at 470 nm to 490 nm.

Special Instructions for Filling Empty Dropper Bottle with Concentrated Hydrochloric Acid:
1. Wear gloves and safety goggles.
2. Place the stock bottle of concentrated hydrochloric acid and the test dropper bottle labeled Concentrated Hydrochloric Acid in a venting hood.
3. Remove cap and dropper tip from dropper bottle.
4. Uncap the stock concentrated hydrochloric acid bottle.
5. Pour acid into test dropper bottle or transfer using a pipette. Avoid breathing acid fumes. Avoid spilling acid.
6. Replace cap on the stock concentrated hydrochloric acid bottle.
7. Holding dropper bottle firmly, force dropper tip into neck of dropper bottle. Screw on cap.
8. In case of contact, flush skin and eyes with copious amounts of water for at least 15 minutes.

Procedure
1. Allow semen sample to liquefy and measure total volume of semen.
2. Pipette 100 µl semen into a test tube.
3. Add 3 drops of Solution A to the test tube.
4. Add 2 drops of Solution B to the test tube and mix.
5. Centrifuge 5 minutes at 1500xg.
6. Pipette 50 µl supernatant into an empty well of the Plate.
7. Pipette 50 µl Fructose Standard into an empty well.
8. Pipette 50 µl water, as a negative control, into an empty well.
9. Add exactly 1 drop Indole to each well.
10. Add exactly 4 drops Concentrated Hydrochloric Acid to each well.
11. Briefly agitate Plate (horizontally) to mix contents. Cover Plate with lid and incubate 30 minutes at 37º C.
12. Read optical density (OD) of wells at 470 nm (or 490 nm) using a microplate reader. First adjust the microplate reader to zero while reading an empty well.

Calculation of Fructose Concentration:

$$[\text{Fructose}] = \frac{\text{OD seminal plasma}}{\text{OD Fructose Standard}} \times 14$$

where 14 is a constant determined by the concentration of fructose in the standard and the dilution of the specimen.

Calculation of Total Amount of Fructose:

$$\text{Fructose} = \frac{[\text{Fructose}]}{1000} \times \text{Volume}$$

Example: At 490 nm the following were obtained for a semen specimen:
Semen Volume = 2 ml
Mean OD of Specimen = 0.255
Mean OD of Fructose Standard = 0.168
OD of Water (negative control) = 0.020

Applying the formula for fructose concentration:

$$\frac{0.255}{0.168} \times 14 = 21.2 \text{ mmol/L [fructose]}$$

Applying the formula for the total amount of fructose:

$$\frac{21.2}{1000} \times 2 = 42.5 \text{ µmol fructose/ejaculate}$$

Performance Characteristics
Intra-Assay Reproducibility

A semen specimen was assayed 10 times for fructose:

Number	Mean (mg)	S.D.	C.V.
10	35.8	± 1.60	4%

EXPECTED RESULTS
If fructose is present in the semen seminal fluid and tested in accordance with this procedure, a fructose concentration can be calculated based on OD of the color reaction.

LIMITATIONS OF PROCEDURES
Ensure that the reagents are performing properly with the use of positive and negative controls. If the expected result is not present with the controls, the semen sample measurement may not be accurate.

BIBLIOGRAPHY
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2. Casals T, Bassas L, Egozcue S, Ramos MD, Giménez J, Segura A, Garcia F, Carrera M, Larriba S, Sarguella J, Estivill X. Heterogeneity for mutations in the CFTR gene and clinical correlations in patients with congenital absence of the vas deferens. Hum Reprod 2000;15:1476-1483.
3. World Health Organization. Laboratory manual for the examination of human semen and sperm-cervical mucus interaction. 3rd ed. New York: Cambridge University Press, 1992.

CONTACT

CalibreScientific US, Inc. offers a complete line of reagents, stains, and QC1™ Quality Control Slides for AFB, Parasitology, Bacteriology, and Mycology processing. CalibreScientific US, Inc. also provides O&P collection systems and concentration devices for Parasitology, as well as products for the evaluation of male fertility. For Technical Assistance, email Technical@AlphaTecSystems.com, and for Customer Service, email Sales@AlphaTecSystems.com, or call either [+1] 800.221.6058 (USA) or [+1] 360.260.2779 between 8AM and 4PM Monday through Friday, Pacific Time.

WARRANTY

This product is warranted by CalibreScientific US, Inc. to perform as described in the labeling and literature supplied. CalibreScientific US, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall CalibreScientific US, Inc. be liable for any consequential damages arising out of aforesaid express warranty.

TRADEMARKS:

FructoScreen® is a trademark of CalibreScientific AMER IP LLC., 6201 Trust Dr, Holland, OH 43528.

PRODUCT CODES:

0006040 FructoScreen, 96 determinations

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GLOSSARY OF SYMBOLS

LOT	Batch code / Numéro de lot / Número de Lote / Numero di lotto / Lot Nummer / Lotnummer / Lotnummer / Šaržna številka / Número de lote
REF	Catalog number / Référence du catalogue / Número de catálogo / Numero di catalogo / Katalognummer / Catalog nummer / Het aantal van de catalogus / Kataloška številka / Número de catálogo
IVD	In vitro diagnostic medical device / Pour usage diagnostique in vitro / Para uso diagnóstico in vitro solamente / Solo per uso diagnostico in vitro / Nur zur Verwendung als in vitro-Diagnostikum / Alleen voor in vitro diagnostisch gebruik / För invitrodiagnostik enbart / Samo za invitro diagnostiko / Apenas para uso em diagnóstico in vitro
EC REP	Authorized representative in the European Community / Représentant européen autorisé / Representante Europeo Autorizado / Rappresentante europeo autorizzato / Autorisierter Europäischer Repräsentant / Germachtigde Europese vertegenwoordiger / Auktoriserad europeisk representant / Pooblaščen evropski predstavnik / Representante Europeu Autorizado
	Use-by date / Utiliser avant la date de péremption indiquée / Use antes de la fecha indicada / Utilizzare entro la data indicata / Bis zum angegebenen datum verbrauchen / Gebruik door vermelde datum / Använd innan angivet datum / Porabiti do navadenega datuma / Usar até à data indicada
	Manufacturer / Fabricant / Fabricante / Produttore / Hersteller / Fabrikant / Fabrikant / Proizvajalec / Fabricante
	Caution / Attention / Cuidado / Attenzione / Achtung / Voorzichtig / Iaktag försiktighet / Previdno / Atenção
	Temperature limit / Conserver aux températures indiquées / Almacene entre las temperaturas indicadas / Conservare a temperature comprese fra quelle indicate / Im angegebenen temperaturbereich aufbewahren / Opslaan bij een temperatuur tussen / Förvara mellan angivna temperaturer / Shranjevati med navedenimi temperaturami / Armazene entre as temperaturas indicadas
Σ	Contains sufficient for <n> tests / Contenu suffisant pour <n> tests / Contiene suficiente para <n> pruebas / Contenuto sufficiente per <n> tests / Enthält ausreichend für <n> untersuchungen / Inhoud voldoende voor <n> testen / Innehåller tillräckligt för <n> tester / Vsebina zadostuje za <n> testov / Contém quantidade suficiente para <n> testes
	Consult instructions for use / Consulter la notice d'utilisation / Consulte las instrucciones para el uso / Consultare le istruzioni per l'uso / Bitte beachten Sie die Anwendungsvorschriften / Raadpleeg instructies voor gebruik / Konsultera bruksanvisningen innan användning / Glej navodila za uporabo / Consulte instruções para o uso
	Do not reuse / Ne pas réutiliser / No reutilizar / Non riutilizzare / Nicht wiederverwenden / Niet hergebruiken / Återanvänd inte / Ne uporabljajte znova / Não reutilize