



Fibronectin Aggrecan Complex Test (FACT™) Molecular Discography™ Sample Collection Kit

Indications

The Fibronectin Aggrecan Complex Test (FACT™) is an enzyme linked immunosorbent sandwich assay (ELISA) that measures the presence of a Fibronectin-Aggrecan Complex (FAC) and other related biomarkers in a fluid specimen taken from patients with spine or joint related pain. FAC is a unique molecular complex that has been reported in peer-reviewed publications to be associated with painful inflammation.

FACT can be used in the assessment of joint or spine related pain in patients greater than 18 years of age who have an acute onset of pain (or an acute exacerbation of baseline pain). A physician may utilize FACT as an adjunct to existing clinical and radiologic information to determine the source of a patient's pain. A fluid specimen can be obtained from the patient prior to treatment, intraoperatively / intraprocedurally upon obtaining access to the disc or joint, or after treatment during a follow up visit. The use of FACT has not yet been evaluated for the assessment of inflammatory arthritides, infectious arthritis, crystalline arthropathies, or autoimmune diseases.

FACT is NOT intended as the sole basis for treatment or disease monitoring decisions. All other available clinical information should be taken into consideration when counseling the patient regarding the treatment of pain. FACT is NOT intended to screen for or predict the outcome of treatments. **Caution: Federal law restricts this device to sale by or on the order of a physician.**

This Laboratory Developed Test was developed and its performance characteristics determined by Cytonics Corporation. Cytonics is regulated under the Clinical Laboratories Improvement Amendments of 1988 and is qualified to perform high-complexity clinical testing (CLIA #10D2007773). FACT has not been cleared or approved by the U.S. Food and Drug Administration.

Instructions For Use: Molecular Discography™ Sample Collection Kit

The Molecular Discography™ Collection Kit includes four collection tubes, each containing a light sensitive protease inhibitor, in a black collection tube pouch together with a Test Request Form. The patient name and date of birth must be included on the collection tubes, on the black collection tube pouch, and on the Test Request Form for sample tracking and patient identification purposes.

Prior to the Procedure: Complete all fields on the Test Request Form and get both the patient's and the physician's signatures.

Specimen Collection Procedure: Disc Lavage for Molecular Discography

1. Premark syringe(s) to correspond with the suspected diseased discs to be lavaged (i.e. Site 1: L3/4, Site 2: L4/5, Site 3: L5/S1, Site 4: S1/S2 for a total of 4 syringes if the physician will be performing a four site Molecular Discography)
2. Attach needle and draw up 2cc of physiologic saline into each syringe and place in the sterile field
3. Position the spinal needle into the center of the disc space, as confirmed by fluoroscopy, image intensifier or ultrasound guidance
4. Attach the syringe that is marked for the site in which the spinal needle has been engaged
5. The physician should then communicate to the circulating nurse which site is being lavaged (i.e. "Lavaging Site 1: L3/4")
6. The nurse should hold the collection tube that is labeled for the site being lavaged
7. The physician will inject the saline into the disc and aspirate using an in / out pumping action to draw fluid back into the syringe
8. The return of saline should take on a slightly cloudy or hazy appearance
9. Detach the syringe from the spinal needle
10. Confirm that the nurse is holding the collection tube labeled for the site that has been lavaged, and transfer the lavasate into the tube
11. Repeat the procedure for each site to be lavaged
12. Notate the site from which each specimen was collected on the Test Request Form

Specimen Packaging and Return Shipment

1. Place collection tubes into the black zip-lock bag and close
2. Insert bag into silver bubble pouch and seal with flap tape
3. Put the pouch in the Cytonics box with the completed Test Request Form and close
4. Place the box into the clear FedEx Clinical Pak and seal with flap tape
5. Call FedEx for pick up: 800-463-3339. Leave at reception desk for pick up
6. Samples must be shipped within 24 hours of collection

For more information, please visit www.Cytonics.com

Or contact us at:

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