UIDL
UI Diagnostic Laboratories

PRENATAL
Facioscapulohumeral Dystrophy (FSHD)
MOLECULAR GENETICS INTERNATIONAL REQUISITION

Information submitted must be in English.

SHIP TO: UI Diagnostic Laboratories
Department of Pathology
200 Hawkins Drive, 5231 RCP
Iowa City, Iowa 52242

Monday – Friday 8:00 am – 6:30 pm CST
Phone: 00-1-319-384-7212
Client Services Fax: 00-1-319-384-7213
Billing Fax: 00-1-319-356-0729

UIDL USE ONLY: MRN# (_____)_____ PATH# _____-_____ **CLIENT Use Only:** Req Date _____ Completed by: _____

Name of Carrier: _____ Tracking Number: _____

Be advised that tracking the delivery time and date of material to the UIDL is the responsibility of the ordering facility.

PART A – PATIENT INFORMATION – *Required*	**PART B – PROVIDER INFORMATION – *Required***
Mother's Last Name:	Referring Facility:
Mother's First Name:	Address:
Date of Birth:	City:
Address:	State/Pr: Country:
City:	Facility Phone:
State/Pr: Country:	**EMAIL for Results:**
Phone:	**Ordering Physician:**
Father's Last Name:	Phone:
Father's First Name:	Email:
Address:	**Genetic Counselor:**
City:	Phone:
State/Pr: Country:	Email:

PART C - SPECIMEN INFORMATION (Complete the appropriate information below)

SPECIMENS REFERRED: Refer to essential information on Facioscapulohumeral Dystrophy (FSHD) Sample Requirements for Prenatal Testing

☐ Maternal Specimen - EDTA (2 pink top) Whole Blood Collection Date: (MM/DD/YY)
☐ Paternal Specimen - EDTA (2 pink top) Whole Blood Collection Date: (MM/DD/YY)
☐ Amniotic Fluid or ☐ Chorionic Villus Specimen Collection Date: (MM/DD/YY)
☐ **Cultured Cells will be shipped separately at a later date**

Deletion of affected parent must be known prior to performing fetal tissue sampling or amniocentesis. Provide 4q35 deletion data here:

_____

Did the University of Iowa test the index case? ☐ Yes ☐ No (check one), or other lab? Please Identify:

_____

This request to order molecular diagnostic tests from University of Iowa Diagnostic Laboratories (UIDL) certifies to UIDL that the ordering physician has obtained informed consent from the patient(s) as required by applicable state or federal laws for each test ordered and that the ordering physician has authorization from the patient(s) permitting UIDL to report results for each test ordered to the ordering physician.

An Importer Certification Statement must be completed and submitted with every international referral case.

Genetic Counseling and Information: By requesting testing, the ordering physician assumes responsibility for providing the patient(s) with all associated guidance and counseling regarding the test results. Alternatively, patients can be referred to qualified counseling services by contacting our client service line at ph.: (866)844-2522.

PART D – REQUIRED BILLING INFORMATION: Specimen will not be processed without completion

☐ **Bill Client** Email Contact Name for Invoicing _____ Email _____

☐ **Prepayment:** If the referring institution is not covering the cost, patient prepayment is required for these services.

Prepay by Check (Payment must come with specimen) Enclosed: Amount $3,900.00* **Check #** _____

Prepay by Credit Card: To initiate the prepayment process, the referring facility (client) must complete the online prepayment submission form available via the below link.
https://medicine.uiowa.edu/uidl/sending-case/billing-options#prepayment
Once received, the UIDL Reference Billing team will process the request and issue a statement of charges along with instructions on how to make the required prepayment using our online payment portal via email to the guarantor.

The purpose of this form is to obtain information necessary for UIDL Pathology Department to perform consultations and/or testing.
Failure to properly complete the form may cause delay in the processing of specimens. *AJC 06.09.2023*

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BILLING:
Credit Card Prepayment of $3900.00 covers the technical and professional charges for the minimal amount of work to begin this testing. For any reason should this prepayment exceed the actual charges incurred, your patient will be refunded, however, please know there may also be additional charges incurred above and beyond the prepaid amount.

TAT:
We perform direct testing for the mutation on a prenatal specimen. There is only one method for this testing and unfortunately it requires a significant amount of DNA to perform. From a timing standpoint, the optimal situation is for the cultures to be ready at 2 weeks after the collection, received by us on a Thursday for processing on a Friday, testing the following week, and a potential result by Monday after. Thus, we say 4 weeks as the minimum time from the CVS collection. However, delays can arise if the timing is not optimal, the cells grow slowly and need extra time or the assay results are difficult to interpret and testing requires repeating by us.

Frequently Asked Questions About FSHD Prenatal Testing
Required Information:
1. The FSHD 4q35 deletion must be known in the parent with FSHD; this may be the EcoRI restriction fragment size in kb or the number of residual D4Z4 repeats.
2. A new blood sample should be submitted from each parent. A new maternal sample is absolutely required. If the affected parent is the father, a paternal sample is also required; this may be either a new blood sample or a residual (stored) material from prior testing in the University of Iowa Molecular Pathology Laboratory.
3. Identify the gestational week of pregnancy.
4. Identify the prenatal sample type, either amniotic fluid or chorionic villi. Arrangements must be made by the referring institution for growing and expanding the cells into at least six, confluent T25 flasks for testing. The confluent T25 flasks are shipped to UI Diagnostic Laboratories. Keeping backup flasks are the referring institution is highly recommended.

FAQs:
Q: Will UI Diagnostic Laboratories accept cultures from another laboratory?
A: Yes. Please send cultured cells directly to:
UI Diagnostic Laboratories
200 Hawkins Drive 5231 RCP
Iowa City IA 52242

Q: Will you accept cells cultured from chorionic villus or amniotic fluid specimens?
A: Yes, we will accept either source of fetal cells. Please note that the time from specimen collection to FSHD testing results is approximately 6-8 weeks. The turn around time relies heavily on the rate at which the cultured cells grow to confluence in at least six T25 flasks.

Q: How many cultured cells does the lab need for testing?
A: Six, confluent T25 flasks are required for testing. Backup flasks held in the cell culture laboratory are highly recommended.

Q: Where do I send the specimens?
A: Please send the parental blood samples and the fetal cell cultures for the case directly to:
UI Diagnostic Laboratories
200 Hawkins Drive 5231 RCP
Iowa City IA 52242

Q: Do I need to send the mother's blood?
A: Yes. A maternal sample is required to rule out maternal cell contamination of the prenatal cell cultures.

Q: Do I need to send the affected parent's blood?
A: Yes. Parental samples are tested side by side with the prenatal specimen. Direct comparisons of the parental and fetal samples improves the accuracy of test interpretation.

Q: Do you need the prior test results of the affected parent?
A: Yes. The affected parent should always be tested to verify the diagnosis of FSHD1 prior to obtaining a prenatal sample.

For additional assistance with specimen packaging and shipping, please refer to FSHD - Prenatal Detection of Abnormal Alleles with Interpretation or call UIDL Client Services 1-866-844-2522.

If additional technical/clinical test information is needed, please contact: Dr. Deqin Ma, Molecular Pathology Laboratory Director, at PrenatalFSHDQuestions@healthcare.uiowa.edu.