U I D L
UI Diagnostic Laboratories

PRENATAL
Facioscapulohumeral Dystrophy (FSHD)
MOLECULAR GENETICS
REQUISITION

UI Diagnostic Laboratories
Department of Pathology
200 Hawkins Drive, 5231 RCP
Iowa City, Iowa 2242
Toll Free: 866-844-2522
Local: 319-384-7212
Client Services Fax: 319-384-7213
Billing Fax: 319-356-0729

FOR UIDL USE ONLY: MRN# PATH#

FOR CLIENT USE ONLY: Requisition Date Completed by:

PART A – PATIENT INFORMATION – *Required*			**PART B – PROVIDER INFORMATION – *Required***		
Mother's Last Name:			**Referring Institution**:		
Mother's First Name:			Address:		
Address:			City:	St:	Zip:
City:	St:	Zip:	Phone:	Fax:	
Phone:	Fax:		Ordering/Contact Physician:	NPI:	Phone:
Date of Birth:			Genetic Counselor (if known):		Phone:
Father's Last Name: Father's First Name:			**If there is another institution, other than the Referring Institution listed above, that has the ultimate financial responsibility for this care:**		
Address:			Name of Institution:		
City:	St:	Zip:	Address:		
Phone:	Fax:		City:	St:	Zip:
Date of Birth:			Phone:	Fax:	

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

Required ICD-10 codes: 1. _____ 2. _____ 3. _____ 4. _____ 5. _____

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.

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 – BILLING – REQUIRED ***SEE Page 2 Backside for important details***

Summary of Billing Options:

☐ **Bill Client** full charges after test completion. Additional information required only if client billing:

On date of collection, was patient: ☐ Inpatient ☐ Outpatient ☐ Non-Hospital Patient

Email Recipient Name for Invoicing: _____

Email Address: _____ **Phone:** _____

☐ **Credit Card Prepayment of $1,907** made prior to receipt of the case via a phone call to the UIDL @ 319-353-7958 or email to marysue-otis@uiowa.edu, or with the case by providing valid and complete credit card information on the UIDL Test Requisition or attaching a check.

The prepayment covers the technical and professional charges for the minimal amount of work to begin FSHD1 and 4qA/4qB Allele 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. Pricing subject to change.

Credit Card: ☐ Visa ☐ MC ☐ DiscoverCard # __ __ __ __-__ __ __ __-__ __ __ __-__ __ __ __ Expires: _____ Pin # __ __ __

Cardholder (Print last name, first name): _____

☐ **Prior Authorization** to support 3rd party payer coverage of services for CPTs outlined on Page 2..

Prior Authorization # (if applicable) _____

This documentation, and a copy of the front and back of the insurance card, must accompany the original UIDL Test Requisition if a 3rd party payer is to be billed. If incomplete 3rd party information is not provided with the specimen, this billing option is not available. *Please collect and send specimens to the UIDL only after prior authorization has been obtained. The UIDL will NOT HOLD testing on specimen while a referring facility waits for 3rd party prior authorization.* ***Note that out of state Medicaid is not accepted and the UIDL is only contracted with BCBS in IA and SD.***

Medicare will only pay for the services that it determines to be "reasonable and necessary" under section 1862(a)(1) of the Medicare Law. If Medicare determines that a particular service, although it would otherwise be covered, is not "reasonable and necessary" under the Medicare standards, Medicare will deny payment for that service or test.

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. *MSO 2/22*

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BILLING:
The following CPT's and 3rd Party Payer pricing will be required by the payer to authorize testing.
CPT 81404 (ZB5J4) x 1 $2,703
CPT G0452 (ZB5J4) x 1 $ 90

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.