F-xxxxxxx # INV.:xxxxxxxx (RÉV.2018-04)

ATTENTION: Zones grises obligatoires

Analyses de laboratoire L-Asparaginase

Analyses de laboratoire L-Asparaginase

CHU Sainte-Justine
Le centre hospitalier universitaire mère-enfant
Université de Montréal

Prise de rendez-vous pour prélèvement : 514 345-4650
3175, Côte Sainte-Catherine, Montréal, QC,H3T 1C5, 514 345-4931

Centre hospitalier : _____

Adresse : Numéro civique Rue _____

Municipalité Pays/Province Code postal

Téléphone : _____ FAX : _____

MD requérant : _____ # Licence : _____

Prélèvement fait: Date: _____ Heure_____

Prélevé par: _____

Cocher obligatoirement la nature de l'échantillon et les analyses requises

SANG : ☐ VEINEUX ☐ ARTÉRIEL
☐ CAPILLAIRE ☐ CORDON OMBILICAL
☐ URINE ☐ SELLES ☐ AUTRE : _____

Identification du patient

Nom, Prénom

Sexe : F ☐ M ☐

Dossier / #Ass. maladie :

Date de naissance :

ou

Plaquer carte

Renseigment clinique: _____

Médicament: L-asparaginase (ASP)

E.Coli ASP ☐ Erwinia ASP ☐ PEG ASP ☐

Pré-dose ☐ Post-dose ☐

Date et heure de la **dernière administration** : _____

Dose : _____ IV ☐ IM ☐

(Ne pas oublier d'inscrire la date et l'heure de prélèvement dans la partie du haut de la requête)

Cet essai de détection de l'activité de la L-asparaginase ("Test") est financé par la pharmaceutique Shire Canada ULC et est sujet aux termes et conditions se trouvant au bas de ce formulaire. En effectuant votre requête et en administrant ce Test, vous (i) acceptez ces termes et conditions et (2) affirmez avoir informé et reçu le consentement de votre patient relativement à ces termes et conditions.

Médecins : _____

Termes et conditions

1. *Ce Test est effectué au seul bénéfice d'un patient pour lequel il est nécessaire et prescrit par son médecin traitant. Ce Test est administré à un patient dans le cadre de son diagnostic et traitement pour une leucémie lymphoblastique aiguë ou une forme de cancer nécessitant la surveillance de l'activité de la L-asparaginase. Il n'est pas prescrit dans le cadre de la recherche.*

2. *Information pour le patient.*

   a. Ce Test est un essai de détection de molécules (drogues) qui a été développé par les laboratoires de pharmacologie clinique du CHU Sainte-Justine. Ce Test n'a pas été approuvé par Santé Canada ni par le Ministère de la santé et des services sociaux du Québec. L'usage des réactifs requis pour la détection des analytes ne requiert pas d'approbation de la Direction des produits thérapeutiques de Santé Canada.

   b. Vous reconnaissez avoir informé votre patient que le Test est offert gratuitement et qu'il ne doit pas demander de compensation ou remboursement sous une quelconque forme par une tierce partie.

3. *Vous reconnaissez que vous ne bénéficierez pas d'un avantage personnel, d'une rémunération ou remboursement en prescrivant ce Test à votre patient.*

4. *Vous reconnaissez que la fourniture et l'administration de ce Test n'est pas et ne fera pas l'objet d'une demande de rémunération ou remboursement par l'établissement, vous-même (médecin traitant) ou votre patient.*

NUMÉRO LABO

F-xxxxxxx # INV.:xxxxxxxx (RÉV.2018-04)
Laboratory analyses L-Asparaginase

ATTENTION: Filing of shaded zones is required

CHU Sainte-Justine
Le centre hospitalier universitaire mère-enfant
Université de Montréal

Laboratory analyses L-Asparaginase

Appointment for blood/urine sampling, call : 514 345-4650
3175, Côte Sainte-Catherine Road, Montreal, QC,H3T 1C5, 514-345-4642

Requesting Institution/Unit : _____
Adress : Civic number Street
Province/Country
Postal code
Phone number: FAX:

Requesting Physician : _____
Sampling Date : Y/M/D Time:
Sampled By : _____

Specify blood sample type and the analyses required

BLOOD : ☐ VENIPUNCTURE ☐ ARTERIAL
☐ CAPILLARY ☐ UMBILICAL CORD
☐ URINE ☐ Other : Specify_____

Patient Information

Last Name, First Name

Gender : F ☐ M ☐

Healt care Institution (specify)
Medicare card # / Health facility file #
D.O.B. :

or

Stamp the patient's Health Care Institution card

Clinical information: _____

Médication: L-asparaginase (ASP)

E.Coli ASP ☐ Erwinia ASP ☐ PEG ASP ☐

Predose ☐ Postdose ☐

Date and time of **last administration** : _____

Dose : _____ IV ☐ IM ☐

(Please do not forget to indicate date and sampling time at the top of the request)

The test for L-asparaginase (ASP) activity ("Test") is funded by Shire Pharma Canada ULC and is subject to the terms and conditions written below. By requesting and administrating this Test, you agree (i) to accept the terms and conditions (see below) of this form and (ii) that you have informed and received agreement of the said terms and conditions from your patient.

Attending physicians : _____

TERMS AND CONDITIONS

1. *The Test is for the sole benefit of a patient who is required to undergo the Test as directed by the patient's attending physician. The Test is administrated to a patient as part of his or her diagnosis and treatment for acute lymphoblastic leukemia or other cancers requiring the monitoring of L-asparaginase activity and is not prescribed in the course of a research project.*

2. *Information for the patient.*

   a. *This Test is a therapeutic drug monitoring assay developed by the CHU Sainte-Justine Clinical Pharmacology laboratory. This Test has not been cleared or approved by Health Canada and the Ministère de la santé et des services sociaux du Québec. Use of the analytespecific reagents in this Test does not require Therapeutic Product Directorate (TPD) approval.*

   b. *You agree that you have informed your patient that this is a free Test and he or she shall not request any form of compensation or reimbursement from any third party, including public or private insurers, for the supply or administration of the Test.*

3. *You agree that you will not receive any personal benefit or remuneration nor reimbursement of financial benefit in providing and administrating this Test to your patient.*

4. *You agree that the supply and administration of this Test is not and will not be included on any claim for remuneration nor reimbursement by any health institution, you (the prescriber) or your patient (the patient).*

LAB NUMBER

Handling of blood samples for monitoring of L-asparaginase activity

1) Preanalytical steps.

1.1 Specimen collection

- Pre-fill the request sheet from CHU Ste-Justine (or another one from your own institution but with similar information) that will accompany the tube until his reception by the analytical lab. The request as well as the document on how to handle blood samples for the monitoring of L-asparaginase activity are now available on our website (scroll down to L-asparaginase)

  https://www.chusj.org/fr/Labotest/Accueil/Requetes

- Draw 1- 3mL of blood into a red top Vacutainer tube (no anticoagulant) or lavender Vacurtainer tube (EDTA). No gel tube..
- Record the date and time that the sample was collected.
- Allow the red top tube to stand at room temperature for 30 minutes to clot (do not place the tube in ice) and then immediately centrifuge or immediately centrifuge the lavender top tube.
- Centrifuge the blood sample at 1,100-1,300 x g for 10 minutes at 25º C.
- Using a disposable pipette, carefully remove the serum or plasma (uppermost clear layer) without disturbing the pelleted blood cells and buffy coat, and transfer it into a 2 mL self-standing polypropylene cryogenic tube with external threads and a rubber toric joint
- If needed (several samples in the same shipment), print vial labels using temperature-resistant labels (ex: USA Scientific Cryotags Item # 9187-1100). Each label must include the name of the patient, date and time the specimen was collected, type of sample (serum or plasma) and the form of L-asparaginase received by the patient (EColi, Erwinia or PEG), Affix the label onto the cryotube. Do not cover the cryovial cap with freezer tape.
- Immediately place the cryotube in a freezer maintained at -70 ºC or lower until packaged for shipment.

1.2 Specimen shipping.

- Samples could be batched and shipped within an appropriate time frame (which largely depends the L-asparaginase form administered to the patient) on via overnight mail to the address listed below. Properly identified sample tubes should be placed within a zip lock plastic bag.

- The plastic bag is packaged in a seamless styrofoam container with 3-4 inches of dry ice on the bottom, and completely covered with an additional 3-4 inches or more of dry-ice.

- The styrofoam container is sealed within a tight-fitting cardboard shipping box. Insert request for samples into a separate zip-lock plastic bag placed on top of the styrofoam container before the external shipping box is sealed.

- **Results : Please make sure to indicate on a separate sheet relevant informations regarding mailing address, fax number, phone number and e-mail of persons to contact for clinical issues.**

- **Billing : Please make sure to indicate on a separate sheet relevant informations regarding mailing address, fax number, phone number and e-mail of persons to contact for financial issues.**

- Before shipping samples, please take into consideration from where the samples would be shipped. If possible, use an overnight courier that would deliver the container by 10 a.m. on the following day. It would be preferable if the container would be delivered on business days of the the same week (Monday to Friday morning) of shipment. If not, put sufficient dry ice into the styrofoam container to take into account that storage over the week-end could possibly take place in an uncontroled environment (ex : room temperature).

- Please ship all samples to:

  Laboratory of the Clinical Pharmacology Unit
  Department of Biochemistry
  Room 2943
  CHU Ste-Justine
  3175, Ste-Catherine Road
  Montreal (Quebec)
  Canada
  H3T 1C5
  Phone: (514) 345-4931 ext 5645
  Fax: (514) 345-4803

2) Analytical steps

- Using L-aspartic β-hydroxamate as substrate, we modified a sensitive microplate reader-based method developed by Lanvers et al (2002) for the quantification of L-asparaginase in the serum or plasma of patients following the administration of L-asparaginase derived from different biological origin (*E. Coli* or *Erwinia chrysanthemi*) or chemically modified enzymes (pegylated *E. Coli* L-asparaginase). In brief, L-asparaginase

hydrolyzed L-aspartic β-hydroxamate to L-aspartic acid and hydroxylamine, which was determined at 710 nm after condensation with 8-hydroxyquinoline and oxidation to indooxine.

- Quantification of L-asparaginase activity in human serum or plasma is done by comparing to low and high range (0,005 to 0,1 IU/l and 0,1 to 1,o IU/l) standard curves generated from increments of each of the respective enzymes (*E.Coli*, *Erwinia* or PEGaspargase)
- L-asparaginase activity in plasma or serum samples is measured during weekdays, usually within 24-48 h after sample reception.

3) Post-analytical steps

- Results (IU/ml) have to be faxed to the sending laboratory (please provide us with the fax number). If you want results to be faxed to a different number, we may do so but consider the extra workload if we have to do so for everyone. Please consider a common fax number for your center. Finally please note that we are using comma as a decimal separator (e.g., 0,450 IU/ml or 1,563 IU/ml).