



## Protamine Response Test (PRT)

### Package Insert English

#### INTENDED USE

The Hemochron PRT is designed for *in vitro* diagnostic protamine dose Response evaluation. Hemochron PRT200 and the PRT400 test tubes are recommended for use in invasive cardiopulmonary bypass procedures requiring protamine for neutralization of heparin anticoagulation. The kaolin-activated PRT assays may also be used for patients receiving aprotinin. The PRT200 and PRT400 should be used with established Hemochron procedural guidelines with Hemochron models 401, 801, 8000 and Response.

*In vitro* Diagnostic Use / For Professional Use / Rx Only

#### SUMMARY AND EXPLANATION

The dose of protamine sulfate required to neutralize heparin after cardiopulmonary bypass surgery is commonly based on a ratio of protamine to the amount of heparin infused during the procedure<sup>1,2</sup>, or on protamine titration.<sup>3,4</sup> Protocols for performing protamine titration have evolved because of the need to determine protamine dosages more accurately than can be derived based solely on empirical considerations.

Accurate determination of protamine dose is advantageous in view of the known complications associated with excess or insufficient protamine.<sup>5,6</sup> Too low a dose may result in heparin-related bleeding, which requires protamine to reverse it. Too high a dose of protamine could result in adverse effects of protamine toxicity. Of equal clinical significance is the observation that the heparin neutralizing potency of protamine varies depending on the manufacturer and lot number.<sup>7</sup> Management of the coagulation state of the cardiopulmonary bypass surgery patient is optimized when these protamine variables are controlled.

The purpose of protamine titration is to determine the exact protamine dosage required to completely neutralize circulating heparin in any given patient. Protamine titration involves performing a clotting time on a heparinized blood sample to which a known amount of protamine has been added. *In vitro* protamine neutralization of heparin correlates with the *in vivo* effects of protamine.<sup>6,11</sup>

#### Protamine Response Test

The PRT may be run in conjunction with the injectable protamine sulfate supplied by the manufacturer. Studies have shown that using the Rx/Dx system gives optimal results and improved clinical data.<sup>12,13,14</sup>

Data show that the PRT in this manner allows accurate prediction of the *in vivo* Response to protamine from an *in vitro* assay.<sup>15</sup>

The PRT200 and PRT400 tests are available with either Celite® (diatomaceous earth) or kaolin activators. The Celite-activated PRT test is not intended for use with the protease inhibitor aprotinin (Trasylol®, Bayer Corporation), which may be administered to reduce post-operative bleeding, especially during cardiopulmonary bypass surgery, and can prolong the Celite-activated PRT. Kaolin is unaffected by moderate doses of aprotinin. The kaolin-activated PRT can be used for protamine dose Response evaluation in patients who are not able to receive aprotinin.

The PRT200 and PRT400 tests contain the reagents required to perform an Activated Clotting Time (ACT) plus an appropriate concentration of protamine. The PRT200 contains 20 µg/ml of protamine, a concentration that corresponds to an average protamine dosage required to neutralize heparin at the end of bypass surgery. The PRT400 contains 40 µg/ml protamine for use in cases requiring large amounts of heparin.

In 1975, Bull et al.<sup>1</sup> published the dose Response curve method, based on the ACT, to individualize heparin and protamine dosages. A method of protamine titration using the Hemochron to automate the performance of the ACT was described.<sup>18,19</sup> The PRT is based on the dose Response curve principle, in minutes (2 mL of patient whole blood) to a clotting time (ACT) of 100 seconds (aprotinin 0.04 mg or 0.08 mg, depending on tube type) of protamine. A protamine Response curve is constructed for the individual patient. Using these results and patient data,<sup>14</sup> the dosage of protamine in *mg* required to neutralize the circulating heparin is determined. The infusion dose is calculated automatically from the Hemochron Response (software version 2.0 or greater) or 8000, or manually using the software provided.

Heparin neutralization can be verified by performing an ACT and PDAO (orange top). See the PDAO package insert for details of this procedure.

#### REAGENTS

The Hemochron PRT test tubes are intended for use with fresh whole blood. The test tubes contain a lyophilized preparation of protamine sulfate with added activator, stabilizers and buffers. The PRT200 and PRT400 test tubes are provided with color coded stoppers:

- Each R-PRT200 tube (peach top) contains protamine sulfate (0.04 mg), diatomaceous earth, stabilizers and buffers.
- Each R-PRT200K tube (peach top) contains protamine sulfate (0.04 mg), kaolin, stabilizers and buffers.
- Each R-PRT400 tube (red top) contains protamine sulfate (0.08 mg), diatomaceous earth, stabilizers and buffers.
- Each R-PRT400K tube (red top) contains protamine sulfate (0.08 mg), kaolin, stabilizers and buffers.

**PRODUCT USE WARNING**

NOTE: Observe universal precautions at all times.

1. The blood specimen should be transferred using an appropriate transfer needle to pierce the stopper.

2. Use a sharp and technique to transfer blood. One hand securely holds the tube while the second hand dispenses the blood specimen from the syringe.

3. The PRT test tubes are made of glass. They can be broken or cracked if mishandled. Do not drop or toss tubes.

4. The PRT test tubes contain a particulate activator (Celite or kaolin) as well as a material of biological origin (protamine sulfate). Do not handle the material, aerosol, or ingest.

5. All used test tubes containing human derived blood should be discarded in approved biohazard containers.

6. Do not remove stoppers to deliver a blood sample to the tube.

#### STORAGE AND STABILITY

The Hemochron PRT tubes should be stored at controlled room temperature (15 - 30°C).

The PRT tubes are stable until the marked expiration date. Avoid prolonged exposure of the PRT kits to temperatures exceeding 30°C.

#### SPECIMEN COLLECTION AND HANDLING

##### Materials Provided

- PRT200 Test tube (peach top; Celite or kaolin-activated, as appropriate).
- PRT400 Test tube (red top; Celite or kaolin-activated, as appropriate).
- PRT worksheet (for manual calculations, if required).

##### Materials Required

- Hemochron Response, 8000, 801 or two 401s.
- Non-silicified, non-heparinized 5 mL syringes for blood specimen collection.
- 20 gauge or larger straight needle for transfer of the blood specimen into the test tube.
- ACT test tube: HRFTCA510 (black top) or HRFTK-ACT (gold top), as appropriate.

**CAUTION: Every precaution should be taken to use proper technique with syringes to avoid accidental needles!**

For blood collection adhere to the appropriate technique (A or B):

- A. Involving venous or arterial blood line. (Do not obtain blood from a heparinized access line or indwelling heparin lock.)
- 1. Discontinue fluid drip, if required.
- 2. Using a two syringe technique, draw two 5 mL syringes and discard the first syringe.

B. Extracorporeal blood line.

1. Flush the extracorporeal blood access line by withdrawing and discarding 5 mL of blood.

2. Draw 5 mL whole blood into a 5 mL syringe.

#### QUALITY CONTROL (QC)

Routine quality control testing and tracking should be a part of a comprehensive quality assurance program. Hemochron Whole Blood Coagulation System Quality Control products are available to make routine QC convenient and affordable.

Daily QC of the Instrument

Hemochron instruments should be quality controlled at two levels of control once every 8 hours of operation. To assist in accomplishing daily QC, Electronic System Verification Tubes are available and can provide multiple level (normal and abnormal) quality control checks on the instrument. A Temperature Verification Tube is also provided for use every 6 months to verify that the instrument is maintaining the proper temperature 37°C ± 1°C. Any errors found in the temperature controls system will also be displayed on the LCD screen by the instrument.

QC of Hemochron Test Tubes

Each box of Hemochron test tubes should be validated at least once prior to use. This can be done by using a complete Hemochron Liquid Control Control.

Acceptable performance ranges for the test tubes are included with each Hemochron Quality Control Product Kit. After each individual box of test tubes has been verified, the "Performance Verified" table provided on the side panel of each test tube box should be completed. This box is now "IN CONTROL" and will not require further liquid quality control unless a shift in clinical results is experienced.

**NOTE: If multiple boxes are received within the same shipment, it is recommended to validate each box prior to use.**

#### TEST PROCEDURE

If using the Hemochron Response (software version 2.0 or higher) or 8000, the system software will quantify the protamine dose based on PRT200 or PRT400 test results and information supplied by the user, along with the status ACT results.

Using the Hemochron Response (software version below 2.0, 801, 401 and the PRT calculator), see the following guideline to determine which PRT tube to use:

PRT200 (peach top): Patient's estimated circulating heparin level at the time of reversal is under 6.5 units/mL.

PRT400 (Red top): Patient's estimated circulating heparin level at the time of reversal is greater than or equal to 6.5 units/mL.

**NOTE: While this guideline is appropriate for most patients, in cases where excessive doses are calculated, repeat testing with the alternative tube may yield a more accurate dose estimation.**

If using Celite-activated PRT tests, an HRFTCA510 (black top) ACT should be used. If using kaolin-activated PRT, an HRFTK-ACT (gold top) should be used.

Recomended Protocols:

1. Prior to heparin neutralization of the patient, obtain the baseline ACT.
2. Once rewarming of the patient has begun, simultaneously perform a PRT test and a status ACT. From the collection syringe, dispense exactly 2.0 mL of blood into the PRT test tube. At the same time, depress the START button of the appropriate Hemochron test well.
3. Immediately agitate the test tube vigorously from end to end ten times.
4. Insert the PRT test tube into the appropriate test well. Quickly rotate the tube clockwise. See the appropriate instrument operator manual for additional information.
5. From the same collection syringe, dispense exactly 2.0 mL of blood into the ACT tube. At the same time, depress the START button of the appropriate Hemochron test well.
6. Immediately agitate the test tube vigorously from end to end ten times.
7. Insert the ACT test tube into the appropriate Hemochron test well. Quickly rotate the tube clockwise. See the appropriate instrument operator manual for additional information.
8. At the indicator tone, record the test result. See Dose Calculations below.

#### Dose Calculations

If using the Hemochron Response (software version 2.0 or higher), refer to the Hemochron Response RxRx Operator Manual for detailed instructions on the use of this automated calculation system. If using the Hemochron 8000, follow instructions in this instrument's operator manual. If using the Hemochron Response with software version 2.0, Hemochron 401 or 801, follow instructions on the PRT worksheet provided in this kit to calculate the protamine dose.

**Calculating Circulating Heparin Intra-procedurally:** This can be done using the Hemochron Response (software version 2.0 or higher) or 8000. Perform a PRT and status ACT. As with any other *in vitro* test procedure, the PRT results should never supersede the clinical judgment of the attending physician.

#### LIMITATIONS OF THE PROCEDURE

1. The accuracy of the protamine dose prediction is dependent upon the accuracy of the patient's calculated blood volume. In some instances, blood volume changes during surgery may be dramatic due to extensive intravenous fluid infusion, urinary loss, or low cardiac output secondary to circulatory collapse. As with any medication by infusion, the user must be aware of these alterations because of their potential effects on the efficacy of the protamine infusion.

2. The use of additional heparin or heparinized blood products (i.e., salvaged red blood cells from the extracorporeal system) following the performance of the PRT assay will negate the test results and protamine prediction. In this circumstance, the PRT should be repeated to reflect the additional protamine requirements. The post-surgical patient should be monitored with the ACT and PDAO to determine the need to infuse additional protamine to compensate for latent heparin effect, which may possibly result in heparin rebound.<sup>17</sup> Should the addition of protamine fail to correct the baseline ACT, an increased coagulopathy should be suspected.

The performance of an ACT and PDAO will demonstrate the presence or absence of aprotinin. The Celite-activated PRT. Kaolin is unaffected by moderate doses of aprotinin. The kaolin-activated PRT can be used for protamine dose Response evaluation in patients who are not able to receive aprotinin.

The PRT200 and PRT400 Tests are intended for use with either Celite® (diatomaceous earth) or kaolin activators. The Celite-activated PRT test is not intended for use with the protease inhibitor aprotinin (Trasylol®, Bayer Corporation), which may be administered to reduce post-operative bleeding, especially during cardiopulmonary bypass surgery, and can prolong the Celite-activated PRT. Kaolin is unaffected by moderate doses of aprotinin. The kaolin-activated PRT can be used for protamine dose Response evaluation in patients who are not able to receive aprotinin.

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## Test de Réponse à la Protamine (PRT)

Notice du produit  
Français / French

### UTILISATION PREDITE

Le kit Hemochron® PRT est conçu pour une évaluation diagnostique *in vitro* de la réponse à des doses de protamine. Les tubes à essais à capuchon pêche PRT200 et à capuchon rouge PRT400 Hemochron sont recommandés durant des interventions chirurgicales cardiaques effractives nécessitant la protamine pour neutraliser l'anticogulation par l'éparine. Les titrages PRT au kaolin actif peuvent également être utilisés pour les patients recevant de l'aprotinine. Les PRT200 et PRT400 doivent être utilisés avec les directives les modalités Hemochron à suivre avec les modèles Hemochron 401, 801, 8000 et Response.

Pour utilisation diagnostique *in vitro*

### SOMMAIRE ET EXPLICATIF

La dose de protamine nécessaire pour neutraliser l'éparine après chirurgie avec circulation extracorporelle est d'habitude basée sur un rapport entre la protamine et la quantité d'éparine perfusée durant l'intervention.<sup>1,2</sup> On suit le tirage de la protamine.<sup>3,4</sup> Les protocoles pour réaliser le tirage de la protamine ont évolué en raison de la nécessité de déterminer la posologie de la protamine avec plus d'exactitude qu'en ne peut le faire en se basant sur des considérations empiriques.

Une détermination exacte des doses de protamine présente des avantages dans le cadre des complications communes associées à l'essai ou à l'insuffisance de l'éparine.<sup>5</sup> Ces faibles doses peuvent engendrer une hémorragie associée à l'éparine et peuvent nécessiter un rappel de protamine. Des doses trop importantes peuvent entraîner des complications supplémentaires de la protamine. D'une manière optimale clinique est l'observation que le potentiel neutralisant de l'éparine de la protamine varie en fonction du fabricant et du numéro de lot.<sup>6</sup> La gestion de l'effet de coagulation d'un patient éprouve avec circulation extracorporelle est optimisée quand les variables relatives à la protamine sont contrôlées.

Le but du tirage de la protamine est de déterminer la posologie exacte de celle-ci qui est nécessaire pour neutraliser complètement l'éparine en circulation chez n'importe quel patient. Le tirage de la protamine implique la réalisation de l'épreuve d'estimation du temps de coagulation sur un échantillon de sang hépariné auquel une quantité connue de protamine a été ajoutée. La neutralisation *in vitro* de l'éparine par la protamine est en corrélation avec les effets en vivo de la protamine.<sup>6,11</sup>

Test de la Réponse à la Protamine  
Le PRT peut être effectué conjointement avec le sulfate de protamine injectable fourni par le fabricant des dispositifs hospitaliers individuels. Des études ont montré que l'utilisation du système RxDx donne des résultats optimaux et améliore les dénouements cliniques.<sup>12,13,14</sup>

Les données indiquent qu'il effectue le PRT de cette manière permet une estimation exacte de la réponse en vivo à la protamine à partir d'un dosage *in vitro*.<sup>15</sup>

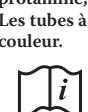
Les tests PRT200 et PRT400 sont disponibles avec des activateurs, soit Celite® (terre d'infusiores), soit kaolin. Le test PRT activé par la terre d'infusiores n'a pas comme but d'être utilisé avec de l'aprotinine, inhibiteur de la protéase (Traystol®, Bayer Corporation), qui peut être administré pour réduire l'hémorragie post-opératoire, partiellement, durant une intervention avec circulation extracorporelle et qui peut prolonger le PRT activé par la terre d'infusiores. Le kaolin n'est pas affecté par des doses modérées d'aprotinine. Le PRT activé par le kaolin peut être utilisé pour une estimation de la réponse des patients à une dose de protamine, qu'ils aient reçus ou non de l'aprotinine.

Le PRT est réalisé en utilisant les modèles d'instruments de coagulation de sang total Hemochron 401, 801, 8000 et Response. Le PRT contient les résultats nécessaires pour réaliser une épreuve de détermination du Temps de Coagulation Activé (ACT), plus une détermination de la concentration appropriée de la protamine. Le PRT200 contient 20 µg/ml de protamine, une concentration qui correspond à la moyenne moyenne de la protamine nécessaire pour neutraliser l'éparine à la fin d'une intervention de pontage. Le PRT400 contient 40 µg/ml de protamine, pour un usage dans les cas nécessitant des importantes quantités d'éparine.

En 1975, Bull et coll.<sup>1</sup> ont publié la méthode de la courbe de réponse aux doses, basée sur l'ACT, afin d'individualiser les posologies de l'éparine et de la protamine. Une méthode de tirage de la protamine, qui utilise l'Hemochron pour automatiser le résultat de l'ACT, a été décrite en 1983.<sup>2</sup> Le PRT reporte sur le principe de la courbe de réponse aux doses. Deux millilitres (2 ml) de sang complet du patient sont utilisés pour déterminer l'ACT et un PRT contenant 0,04 mg ou 0,08 mg (en fonction du type de tube) de protamine. Une courbe de la protamine est tracée pour chaque patient. En lisant les résultats et les données relatives au patient, la posologie de la protamine en présence pour neutraliser l'éparine en circulation est déterminée. La dose à perfuser est automatiquement calculée par le modèle Hemochron Response (version du logiciel 2,0 ou ultérieure) ou 8000, ou bien manuellement en utilisant les feuilles de travail fournies.

La neutralisation de l'éparine peut être vérifiée en déterminer l'ACT et un PDA (capuchon orange). Se reporter à la notice du PDA pour des renseignements au sujet de cette procédure.

**REACTIFS**  
Les tubes à essais du kit Hemochron PRT sont conçus pour être utilisés avec du sang complet frais. Les tubes à essais contiennent une préparation hypolipidante de sulfate de protamine, laquelle a été ajoutée un activateur, des stabilisateurs et des tampons. Les tubes à essais des kits PRT200 et PRT400 sont fournis avec des capuchons avec code couleur.



- Chaque tube du kit PRT200 (capuchon pêche) contient du sulfate de protamine (0,04 mg), de la terre d'infusiores, des stabilisateurs et des tampons.
- Chaque tube du kit R-PRT200 (capuchon pêche) contient du sulfate de protamine (0,04 mg), du kaolin, des stabilisateurs et des tampons.
- Chaque tube du kit R-PRT400 (capuchon rouge) contient du sulfate de protamine (0,08 mg), de la terre d'infusiores, des stabilisateurs et des tampons.
- Chaque tube du kit R-PRT400K (capuchon rouge) contient du sulfate de protamine (0,08 mg), du kaolin, des stabilisateurs et des tampons.

### MISE EN GARDE CONCERNANT L'USAGE DU PRODUIT

REMARQUE : Suivre les précautions universelles à tout moment.

1. L'épreuve de la protamine doit être réalisée en utilisant une seringue de transfert appropriée pour percevoir le bordage.

2. Toujours utiliser la technique à deux mains pour transférer le sang. Une main maintient fermement le tube tandis que la seconde main verse l'échantillon sanguin contenu dans la seringue.

3. Les tubes à essai PRT sont en verre. Ils peuvent être cassés ou fissurés en cas de mauvaise manipulation. Ne pas tomber ou lancer les tubes.

4. Les tubes à essai PRT contiennent un activateur particulaire (terre d'infusiores ou kaolin), ainsi qu'un produit d'origine animale (sulfate de protamine). Ne pas manipuler le produit, le vaporiser ou l'ingerer.

5. Tous les tubes à essai humain doivent être mis au rebut dans des contenants pour objets contaminiés aiguillons.

6. Ne pas répéter les bouclettes pour déposer un échantillon sanguin dans le tube.

### CONSERVATION ET STABILITE

Tous les tubes du kit Hemochron PRT doivent être conservés à température ambiante contrôlée (15 – 30°C). Les tubes du kit PRT restent stables jusqu'à la date de péremption marquée. Éviter une exposition prolongée des kits PRT à des températures dépassant 30°C.

### PRELEVEMENT ET MANIPULATION DES ECHANTILLONS

Matériel fourni

- Tube à essai PRT200 (capuchon pêche) : activé par de la terre d'infusiores ou du kaolin, selon le cas.
- Tube à essai PRT400 (capuchon rouge) : activé par de la terre d'infusiores ou du kaolin, selon le cas.
- Feuille de travail (pour les calculs manuels, si nécessaire).

Matériel requi

- Hemochron Response, 8000, 801 ou deux 401.
- Seringues de 5 mL non siliconées, pour la collecte d'échantillons sanguins.
- Une aiguille droite de calibre 20 ou plus large pour transférer l'échantillon sanguin dans le tube à essai.
- Un tube à essai pour ACT : HRFTCA510 (capuchon noir) ou HRFTK-ACT (capuchon orange), selon le cas.

ATTENTION ! Toutes les précautions doivent être prises pour utiliser la technique qui convient avec les seringues afin d'éviter de se piquer accidentellement avec l'aiguille.

Pour la collecte du sang, suivre la technique qui convient (A ou B) :

A. Tubule à demeure pour sang veineux ou artériel. (Ne pas obtenir de sang à partir d'une tubule d'accès hépariné ou un dispositif verrouillable à demeure pour l'éparine).

1. Arrêtez la perfusion des fluides, si nécessaire.

2. Enlever la seringue à deux seringues, remplir deux seringues de 5 mL puis mettre au rebut la première seringue.

B. Orifice de la tubule de la circulation extracorporelle

1. Rincer la tubule d'accès à la circulation extra-corporelle en prélevant et en jetant 5 mL de sang.

2. Prélever 5 mL de sang complet dans une seringue de 5 mL.

### CONTROLE DE LA QUALITE (QC)

Un contrôle de la qualité et un suivi systématiques doivent faire partie du programme d'assurance de la qualité complet. Des produits de contrôle de la qualité des systèmes de coagulation du sang entier Hemochron sont disponibles afin de rendre le contrôle de la qualité systématique plus facile et plus abordable.

QC quotidien de l'instrument

Les patients doivent savoir ou contrôler de la qualité avec témoins à deux concentrations après chaque période de 8 heures de fonctionnement. Pour aider à accomplir le QC, quotidiens des tubes pour vérification des systèmes électroniques sont disponibles et ils peuvent servir à effectuer des vérifications de contrôle de la qualité de l'instrument avec plusieurs concentrations (normale et anormale). Un tube de vérification de la température est également fourni et il doit être utilisé tous les 6 mois pour vérifier que l'instrument maintient la température appropriée de 37°C ± 1°C. Toute erreur trouvée dans le système de contrôle de la température sera aussi affichée sur l'écran LCD de l'instrument.

Contrôle de la qualité des tubes à essais Hemochron  
Chaque boîte de test à essai Hemochron contient une valise valable au moins une fois avant son utilisation. C'est pour être réalisé en utilisant le contrôle de la qualité liquide Hemochron approprié. Des plages de performances acceptables pour les tubes à essais sont comprises dans chaque kit de produits de contrôle de la qualité Hemochron. Dès que chaque boîte individuelle de tubes à essai a été vérifiée, le tableau « Performance vérifiée » présent sur le panneau latéral de chaque boîte de tubes à essai doit être complété. Cette boîte se trouve maintenant « IN CONTROL » et elle ne nécessitera pas de contrôle de la qualité liquide supplémentaire, à moins que les résultats cliniques observés aient changé.

REMARQUE : Dans le cas de la réception de boîtes multiples au sein d'un même envoi, il est recommandé de valider chaque boîte avant son utilisation.

**TEST DE RÉPONSE À LA PROTAMINE (PRT)**

Foglio illustrativo  
Italiano / Italian

## Test di risposta alla protamina (PRT)

Foglio illustrativo  
Italiano / Italian

### INDICATIONS PER L'USO

Hemochron® PRT est conçu pour une évaluation diagnostique *in vitro* de la réponse à des doses de protamine. Les tubes à essais à capuchon pêche PRT200 et à capuchon rouge PRT400 Hemochron sont recommandés durant des interventions chirurgicales cardiaques effractives nécessitant la protamine pour neutraliser l'anticogulation par l'éparine. Les titrages PRT au kaolin actif peuvent également être utilisés pour les patients recevant de l'aprotinine. Les PRT200 et PRT400 doivent être utilisés avec les directives les modalités Hemochron à suivre avec les modèles Hemochron 401, 801, 8000 et Response.

Pour utilisation diagnostique *in vitro*

**PROCEDURE DU TEST**  
Si on utilise le kit Hemochron Response (version du logiciel 2,0 ou ultérieure) ou 8000, le logiciel quantifie la dose de protamine en base agli esiti del test PRT200 o PRT400 e alle informazioni fornite dall'utente, come anche ai risultati della prova.

Se si utilizza invece il kit Hemochron Response (versione software precedente a 2,0, 401, 801 e 8000), è necessario calcolare la linea guida seguente per determinare quale prova PRT usare:

PRT 200 (tappo arancio): Il livello stimato di paramina circolante del paziente al momento dell'inversione è inferiore a 6,5 unità/ml.

PRT 400 (tappo rosso): Il livello stimato di paramina circolante del paziente al momento dell'inversione è superiore a 6,5 unità/ml.

NOTA: Questa linea guida risulta idonea per gran parte dei pazienti, tuttavia se si calcola dosi eccessive, la ripetizione del test con la provetta alternativa può fornire una stima più precisa della dose.

Con i test PRT attivati con Celite, utilizzare una provetta ACT PTCA510 (tappo nero).

Con i test PRT attivati con caolin, utilizzare una provetta HRFTK-ACT (tappo arancio).

Per uso diagnostico invitare

**RIASSUNTO E SPIEGAZIONE**  
La dose di protamina necessaria per neutralizzare l'éparine a fronte delle noci complicate associate a essa per la neutralizzazione dell'éparine a seguito di bypass cardiopulmonare è basata normalmente su un rapporto fra protamina e il volume di epine infuso durante la procedure.<sup>1,2</sup> È generalmente sottile la titulazione di protamina.<sup>3,4</sup> Per via dell'esigenza di determinare le dosi di protamina con precisione maggiore rispetto a quanto possibile con le sole considerazioni di tipo empirico, si è assistito all'evoluzione di protocolli per la titulazione.

L'accurata determinazione della dose di protamina risulta vantaggiosa a fronte delle noci complicate associate a essa per la neutralizzazione dell'éparine a seguito di bypass cardiopulmonare, e generalmente basata sulla proporzionalità fra protamina e il volume di epine infusa durante la procedura.<sup>1,2</sup> È generalmente sottile la titulazione di protamina.<sup>3,4</sup> Per via dell'esigenza di determinare le dosi di protamina con precisione maggiore rispetto a quanto possibile con le sole considerazioni di tipo empirico, si è assistito all'evoluzione di protocolli per la titulazione.

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