# KOAGÜLASYON LABORATUVARINDA KALİTE

**Uzm. Dr. Merve Sibel Güngören**

Düzen Laboratuvarlar Grubu

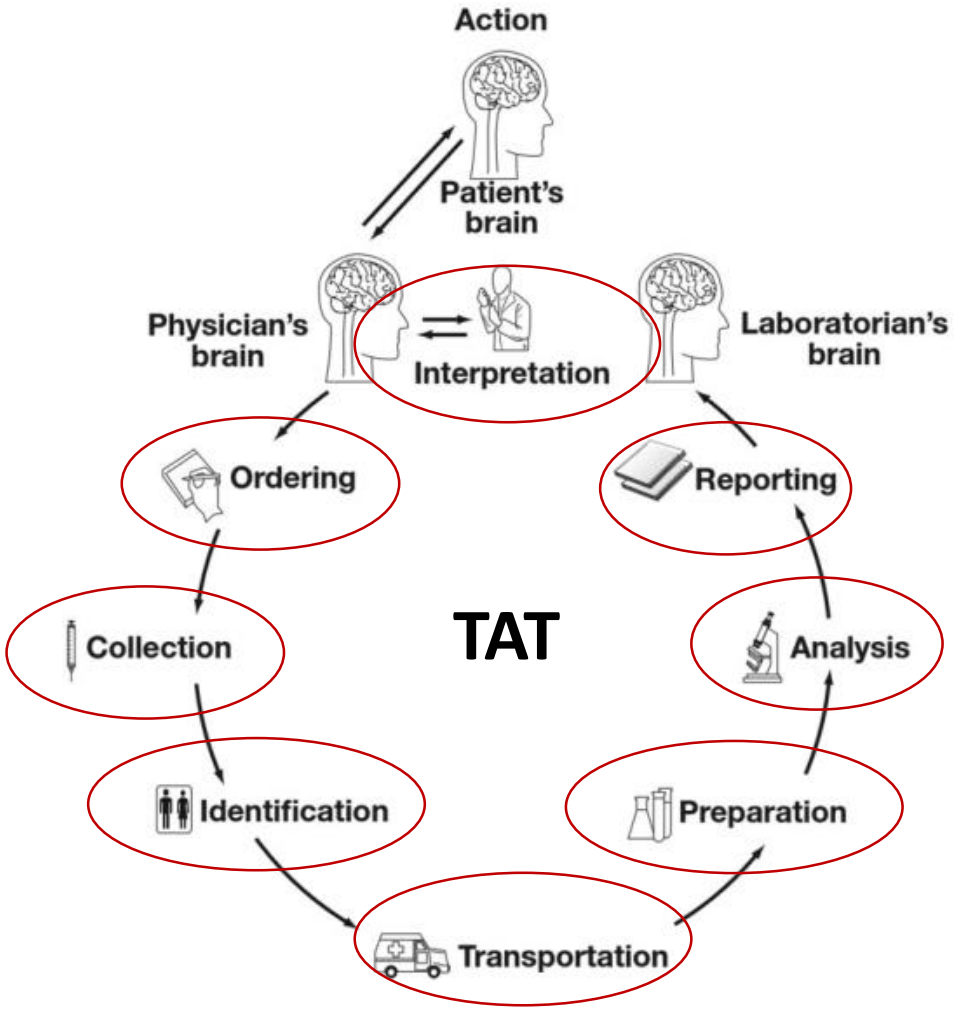
# Laboratuvar Testlerinde Kalite

Laboratory
Quality
Management

## Definition of quality

Laboratory quality can be defined as accuracy, reliability and timeliness of reported test results. The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting.

# Kaliteli Test ne anlama gelir?



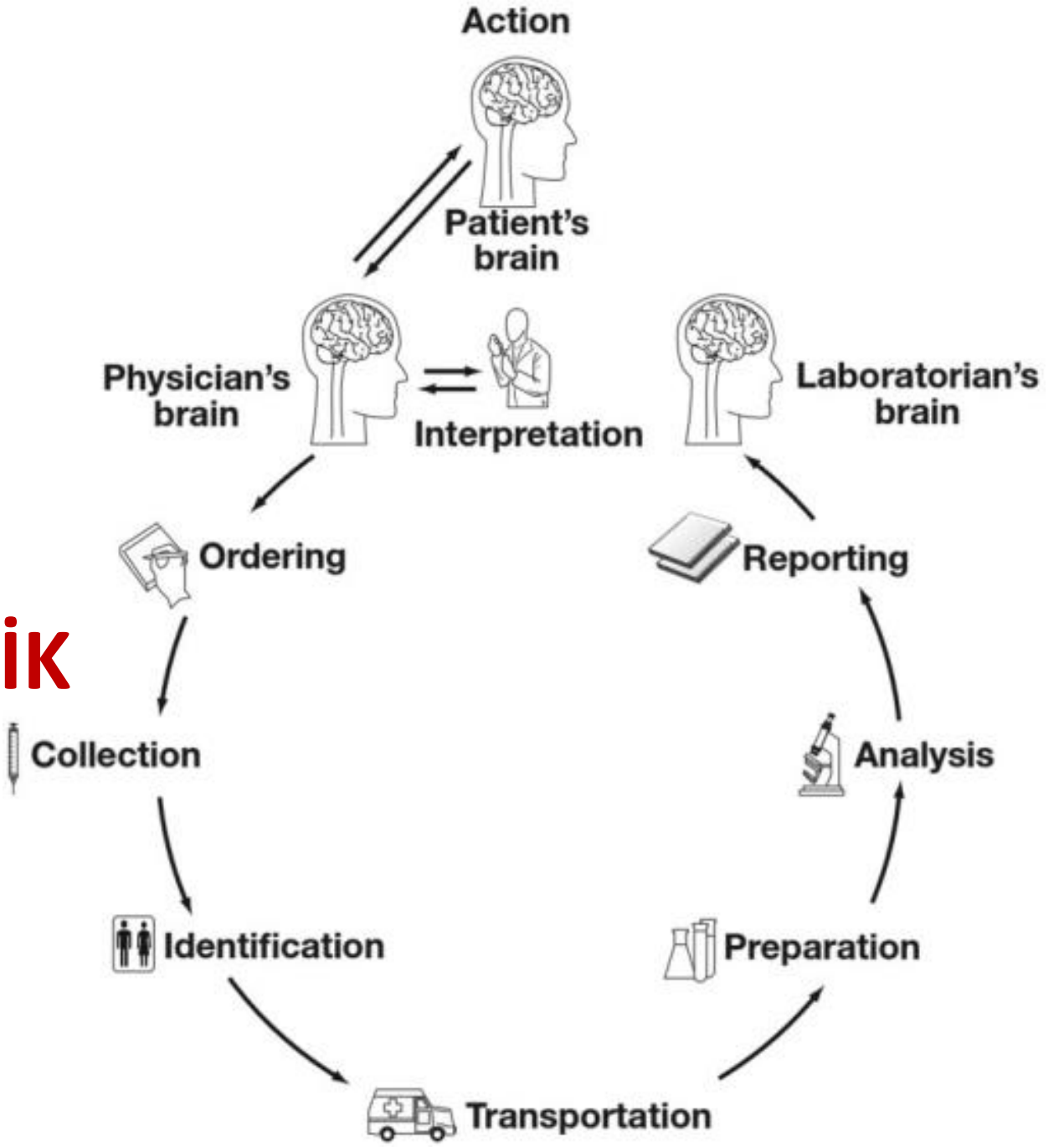

Plebani M, Laposata M, Lundberg GD. The brain-to-brain loop concept for laboratory testing 40 years after its introduction. Am J Clin Pathol. 2011 Dec;136(6):829-33.

# Koagülasyon Testlerinde Kalite

Testin kalitesi =Hasta güvenliği

Toplam test sürecinin her basamağında kalitenin sağlanması gerekli

# PREANALİTİK EVRE



# Preanalitik Kalite – Genel Sorunlar

- Test isteminin olmaması – yanlış olması
- Örneğin laboratuvara ulaşmaması
- Hatalı etiketleme
- İnfüzyon ile kontaminasyon
- Hemolizli/pıhtılı/yetersiz örnek
- Uygun olmayan antikoagülan/kan oranı
- Uygun olmayan transfer ve saklama koşulları

Lippi G, Guidi GC, Mattiuzzi C, Plebani M. Preanalytical variability: the dark side of the moon in laboratory testing. Clin Chem Lab Med. 2006;44(4):358-65.

# Preanalitik Kalite

## Test isteminde sorunlar

Bilgi eksikliği

Artan kompleks test sayısı

Kılavuzların takibinde eksiklik

Alternatif antikoagülanlara uygun testlerin henüz bulunmaması

Klinik – laboratuvar iletişiminde sorunlar

Tufano A, et al. Prevention of venous thromboembolism in medical patients with thrombocytopenia or with platelet dysfunction: a review of the literature. Semin Thromb Hemost. 2011 Apr;37(3):267-74.

Bikdeli B, Sharif-Kashani B. Prophylaxis for venous thromboembolism: a great global divide between expert guidelines and clinical practice? Semin Thromb Hemost. 2012 Mar;38(2):144-55.

# Preanalitik Kalite

## Uygunsuz/gereksiz test isteminde çözümler

Geri bildirim

Eğitim

Bilgisayar yardımlı test istemi – LBYS'de algoritmalar

Talep yönetimi kılavuzları

Refleks ve reflektif test kullanımı – daha proaktif bir laboratuvar

Plebani M, Favaloro EJ, Lippi G. Patient safety and quality in laboratory and hemostasis testing: a renewed loop? Semin Thromb Hemost. 2012 Sep;38(6):553-8.

**TABLE 1** *Choosing Wisely* recommendations related to hematology and coagulation laboratory testing.[4] ASA: American Society of Anesthesiologists, MTHFR: methylenetetrahydrofolate reductase, HFE: hemochromatosis gene

| Category | Recommendation | Society |
|---|---|---|
| Serial blood counts | Don't perform serial blood counts on clinically stable patients | AABB |
| | Don't order diagnostic tests at regular intervals (such as every day), but rather in response to specific clinical questions | Critical Care Societies Collaborative |
| | Don't perform repetitive CBC and chemistry testing in the face of clinical and lab stability | Society of Hospital Medicine |
| Thrombophilia testing | Don't test for thrombophilia in adult patients with venous thromboembolism (VTE) occurring in the setting of major transient risk factors (surgery, trauma, or prolonged immobility) | American Society of Hematology |
| | Don't routinely order thrombophilia testing on patients undergoing routine infertility evaluation | American Society for Reproductive Medicine |
| | Don't do an inherited thrombophilia evaluation for women with histories of pregnancy loss, intrauterine growth retardation (IUGR), preeclampsia, and abruption | Society for Maternal-Fetal Medicine |
| | Don't do work up for clotting disorder (order hypercoagulable testing) for patients who develop first episode of deep vein thrombosis (DVT) in the setting of a known cause | Society for Vascular Medicine |
| Preoperative blood count and coagulation testing | Don't obtain baseline laboratory studies in patients without significant systemic disease (ASA I or II) undergoing low-risk surgery—specifically complete blood count, basic or comprehensive metabolic panel—coagulation studies when blood loss (or fluid shifts) is/are expected to be minimal | American Society of Anesthesiologists |
| | Avoid routine preoperative testing for low-risk surgeries without a clinical indication | American Society for Clinical Pathology |
| | Don't perform routine preoperative testing before low-risk surgical procedures | Society of General Internal Medicine |

| | | |
|---|---|---|
| Genetic testing for hematologic disorders | Don't order MTHFR genetic testing for the risk assessment of hereditary thrombophilia | American College of Medical Genetics and Genomics |
| | Don't order HFE genetic testing for a patient without iron overload or a family history of HFE-associated hereditary hemochromatosis | American College of Medical Genetics and Genomics |
| Other | In patients with low pretest probability of venous thromboembolism (VTE), obtain a high-sensitive D-dimer measurement as the initial diagnostic test; don't obtain imaging studies as the initial diagnostic test | American College of Physicians |
| | Don't use bleeding time test to guide patient care | American Society for Clinical Pathology |
| | Don't order an erythrocyte sedimentation rate (ESR) to look for inflammation in patients with undiagnosed conditions. Order a C-reactive protein (CRP) to detect acute phase inflammation | American Society for Clinical Pathology |
| | Don't test vitamin K levels unless the patient has an abnormal international normalized ratio (INR) and does not respond to vitamin K therapy | American Society for Clinical Pathology |
| | Don't test or treat for suspected heparin-induced thrombocytopenia (HIT) in patients with a low pretest probability of HIT | American Society of Hematology |

# Preanalitik Değişkenler – Hasta kaynaklı

- Açlık tokluk durumu – açlık öneriliyor; hafif öğünün etkisi?
- Gebelik – FVIII, fibrinojen artışı; plt, vWF, prt S azalışı
- Egzersiz, kahve, sigara – trombosit fonksiyon testleri
- Sirkadiyen ritm (agregasyon en fazla sabah) – TFT
- Yüksek veya düşük hematokrit
- Egzersiz
- Tedavi durumu – K vitamini, heparin, DOAC

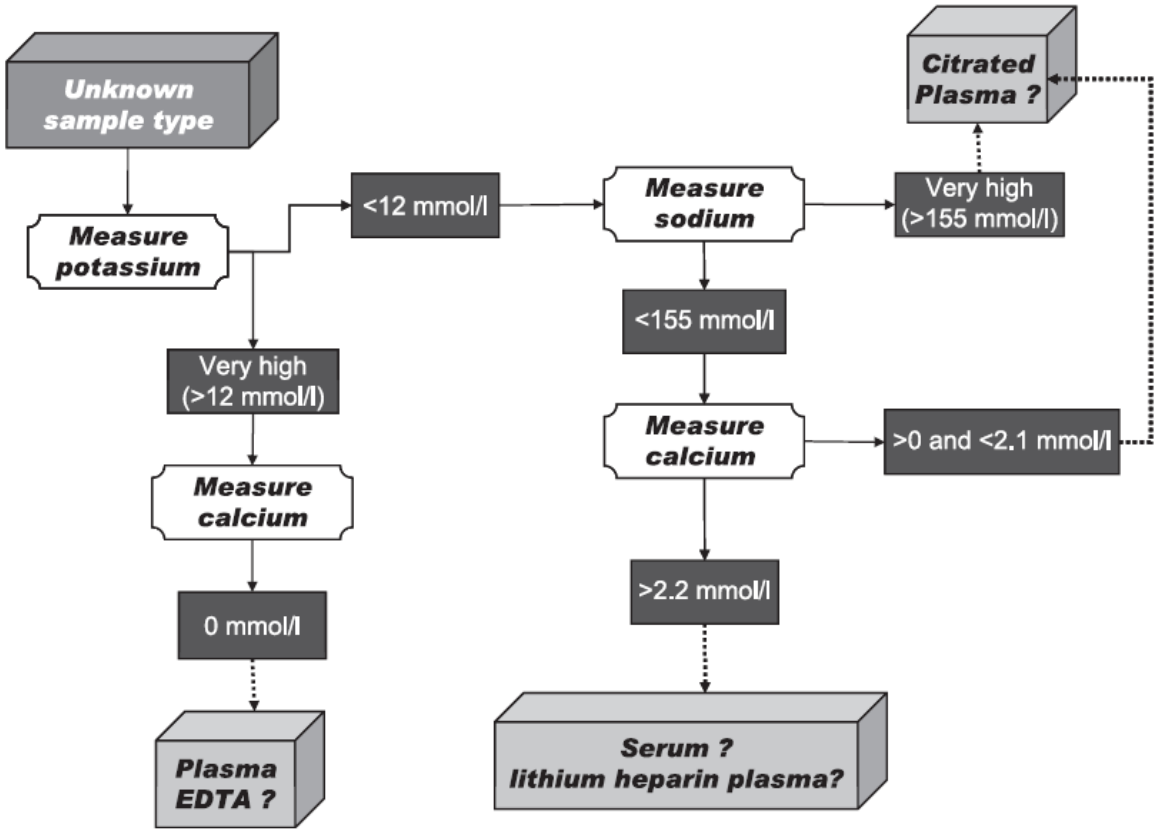
Int. J. Mol. Sci. **2017**, 18, 1803 | Methods Mol Biol. 2017;1646:305-320

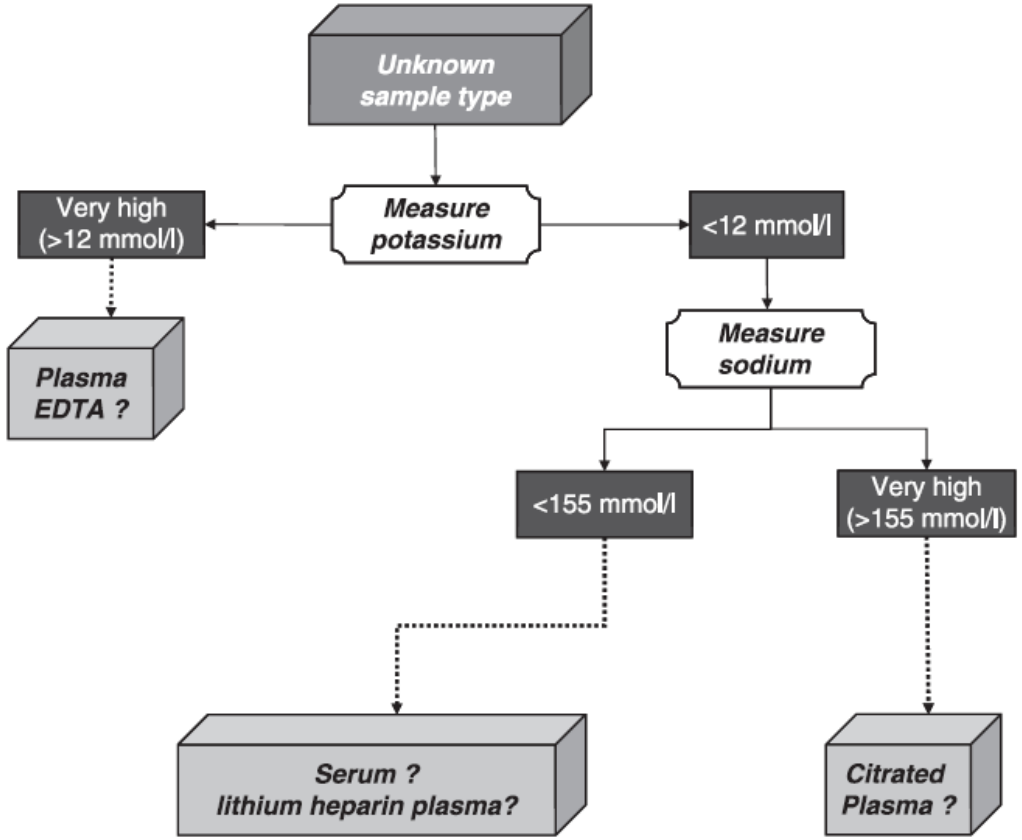
# Örnek Alımı

- Sıkı turnike uygulamasından kaçınılmalı
- En az 21 gauge enjektör
- Minimal travmatik, düzgün kan akımı
- Anında 3 – 6 kez karıştırma
- Miktar kontrolü; işaretli seviyeye kadar dolum
- Aşırı  karıştırma-sallamaya maruz kalmamalı
- Sitratlı tüp: Trisodyum sitrat 109 mM (3.2%) veya 129 mM (3.8%)

Br J Haematol 2011; 155: pp. 30-44

# Sekonder Tüp Kullanımı - Yanlış Örnek Gönderilmesi

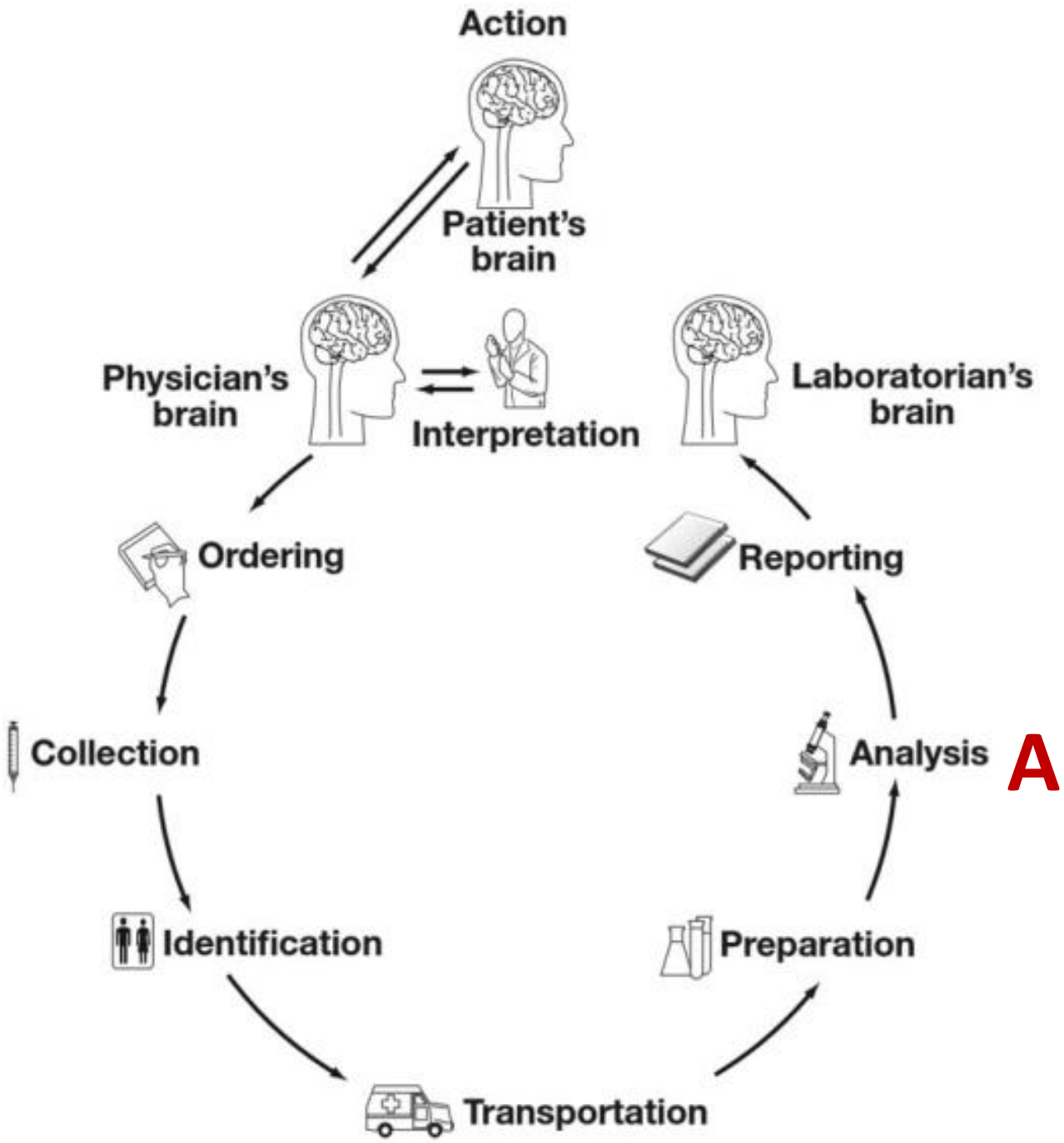



Lippi G, et al. Right or wrong sample received for coagulation testing? Tentative algorithms for detection of an incorrect type of sample. Int J Lab Hematol. 2010 Feb;32(1 Pt 2):132-8.

# Örnek transferi – stabilite sorunları

- Oda sıcaklığında transfer – en geç 1 saat içinde
- Trombosit fonksiyon testleri – en geç 3-4 saat içinde
- Pnömatik sistem uygun değil
- Dondurularak saklanan örnekler – en fazla 15 gün
- Don-çöz döngüsünü tekrarlamak uygun değil




# ANALİTİK EVRE

# Analitik Kalite – İç Kalite Kontrol

- Kanada'da PT ve APTT çalışan 174 laboratuvarda yapılan anket
- İKK uygulamaları hakkında bilgi amaçlı
- Laboratuvarların tamamı (% 100) 2 düzey İKK çalışıyor
- % 12'si ilave olarak hasta örneğinden oluşturulan havuz numunesi de kullanıyor

MacFarlane A, et al. **Internal Quality Control Practices in Coagulation Laboratories: recommendations based on a patterns-of-practice survey** IJLH 2015 729-738..

# Analitik Kalite – İç Kalite Kontrol

İKK sıklığı:

- % 68'i her vardiya başı İKK örneği çalışıyor
- % 6'sı her günün başlangıcında İKK örneği çalışıyor
- % 56'sı bakım, reaktif değişikliği, vardiya esnasında, her tekrar örneği ile İKK örneği çalışıyor
- % 25'i belli bir süre cihaz çalışmayınca da İKK çalışıyor

MacFarlane A, et al. **Internal Quality Control Practices in Coagulation Laboratories: recommendations based on a patterns-of-practice survey** IJLH 2015 729-738..

# İç Kalite Kontrol

- % 71'i üretici önerisine göre İKK sıklığını belirliyor
- % 27'si testin stabilitesine göre İKK sıklığını belirliyor
- % 27'si hatalı sonucun klinik önemine göre İKK sıklığını belirliyor

MacFarlane A, et al. **Internal Quality Control Practices in Coagulation Laboratories: recommendations based on a patterns-of-practice survey** IJLH 2015 729-738..

# İç Kalite Kontrol

İKK sınırları:

% 66 – SD

% 46 – Kesinlik hedefleri

% 36 – İzin verilebilir limitler

İKK Değerlendirme:

% 95 Multirule!!!

MacFarlane A, et al. **Internal Quality Control Practices in Coagulation Laboratories: recommendations based on a patterns-of-practice survey** IJLH 2015 729-738..

# İç Kalite Kontrol

İKK sonucu  kabul edilebilir değil ise

% 90 – İKK tekrarı, ancak hasta sonucu veriliyor

% 42 – bir önceki QC'den tüm hastaları tekrar ediyor

MacFarlane A, et al. **Internal Quality Control Practices in Coagulation Laboratories: recommendations based on a patterns-of-practice survey** IJLH 2015 729-738..

| Test Adı | Düzey 1 kontrol hedefi | Düzey 2 kontrol hedefi | Ek öneriler |
|---|---|---|---|
| **Rutin koagülasyon testleri (PZ, INR, APTZ, TZ)** | Referans aralığın orta noktası | Terapötik aralığın orta noktası (yüksek düzey) | Terapötik/anormal aralığın üst noktası |
| **Fibrinojen** | Referans aralığın orta veya alt noktası | Anormal (düşük düzey) aralığın orta noktası | Tromboz riski varsa aralığın üst noktası |
| **D-dimer** | Normal aralığın orta veya alt noktası (negatif kontrol) | Anormal (pozitif) aralığın orta noktası (pozitif kontrol) | DIC monitorizasyonunda aralığın üst sınırı |
| **Faktör testleri (FII,VII, VIII, IX, X, XI, XII)** | Referans aralığın orta veya alt noktası (ör, %90-100) | Anormal (düşük düzey) aralığın orta noktası (ör, %20-40) | Faktör eksik plazma – testin alt sınırı için; aralığın üst noktası – tromboz riski için |
| **FXIII** | Normal plazma (negatif kontrol) | FXIII eksik plazma (pozitif kontrol) | |
| **vWF testi** | Referans aralığın orta veya alt noktası (ör, %90-100) | Anormal (düşük düzey) aralığın orta noktası (ör, %20-40) | vWF eksik plazma – testin alt sınırı için; aralığın üst noktası – tromboz riski için; kalitatif kontrol |
| **Protein C, Protein S, Anti-trombin testleri** | Referans aralığın orta veya alt noktası | Anormal (düşük düzey) aralığın orta noktası veya heterozigot kontrol | |
| **Aktive protein C rezistansı** | Referans aralığın orta veya alt noktası | Anormal (düşük düzey) aralığın orta noktası veya heterozigot kontrol | |
| **Lupus antikoagülan testi** | Negatif kontrol | Pozitif kontrol (zayıf pozitif veya eşik değer civarı) | Pozitif kontrol (orta veya kuvvetli pozitif) |

Bonar, et al. **Internal Quality in Coagulation and Hemostasis Testing. Biochemia Medica 2010;20(2):184-99.**

# Analitik Kalite

- Hasta sonucu bazlı QC???

- Literatürde koagülasyon testlerinde yeri???

# Analitik Kalite

- Koagülasyon testlerinde hasta başı testleri (POCT)
- Henüz çok yaygın değil
- Hastalara eğitim gerekli
- Kliniklerde kullanıcı eğitimi???

# Dış Kalite Değerlendirme

- Koagülasyon testlerinde kullanımı

- Örnek tipi? – plazma
- Liyofilize

Contrived samples – doğal olmayan örnekler

- Faktör testleri
- Trombofili testleri
- vWF değerlendirmesi

- SF ile dilue örnekler???

# Dış Kalite Değerlendirme

- DKD test menüsünün genişliği?
- Programın sıklığı?
- DKD sonuçlarının değerlendirilmesi

# Dış Kalite Değerlendirme

- Konvansiyonel DKD programları

Analitik DKD

- Ekstra-analitik kısmın değerlendirilmesi???

# Dış Kalite Değerlendirme

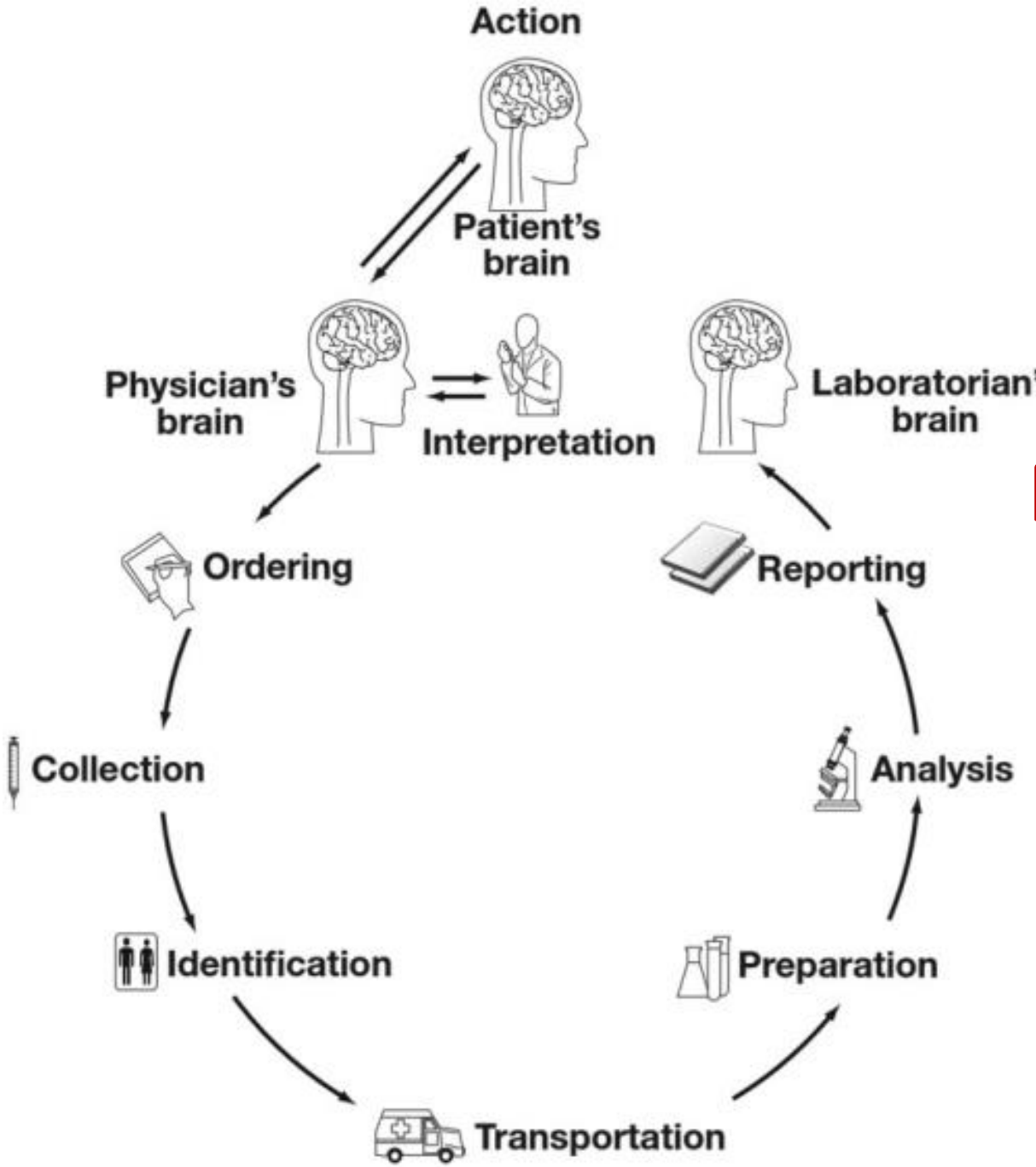
- Integrated EQA – bütünleşik DKD

- ISO 15189:2012 5.6.3.1 ile uyumlu – analiz dışında analiz öncesi ve sonrası prosedürlerin de gözden geçirildiği bir laboratuvarlar arası karşılaştırma programı

- Örnek: LabQuality D-dimer
  Preanalitik vakalar – elektronik ortam
  Sorunlu örnekler (normal örneklerin dışında)
  Postanalitik vakalar – elektronik ortam

NASCOLA EQA (ABD)

Labquality - EQAS




# POSTANALİTİK EVRE

# Postanalitik Kalite

- Birimler konusunda klinisyenin dikkati çekilmeli
- Örnek: D-Dimer
- 1 ng/mL DDU = 2 ng/mL FEU
- D-Dimer Unit
- Fibrinogen Equivalent Unit

# Postanalitik Kalite – Kritik Değerler

**Table 1.** Essential elements of critical laboratory values in hemostasis testing as for current literature.

| | CLSI | IFCC | CAP[a] | CCMB | NASCOLA[b] | Campbell et al[b] | Piva et al[b] |
|---|---|---|---|---|---|---|---|
| References | (8) | (27) | (23) | (29) | (24) | (26) | (28) |
| APTT (sec) | | | | | | | |
| Low | – | – | <16.2 | – | – | <12.0 | – |
| High | >100 | >75 | >92.9 | >75 | >100 | >82.5 | >85 |
| APTT (ratio) | | | | | | | |
| Low | – | – | – | – | – | – | – |
| High | – | – | – | – | – | – | – |
| PT (sec) | | | | | | | |
| Low | – | | – | <15 | – | <8 | – |
| High | – | | – | >40 | >37 | >30 | – |
| PT (ratio) | | | | | | | |
| Low | – | | – | – | – | – | – |
| High | – | | – | – | – | – | – |
| PT (INR) | | | | | | | |
| Low | – | | – | – | – | – | – |
| High | ≥5.0 | | – | ≥5.0 | >5.0 | >4.75 | – |
| Fibrinogen (g/L) | | | | | | | |
| Low | – | <0.8 | – | <0.8 | <1.0 | <1.0 | – |
| High | – | – | – | – | – | >7.0 | – |
| Platelet count ($\times 10^9$/L) | | | | | | | |
| Low | <40[(c)] | <20 | <38.5 | <20 | – | <20 | <30 |
| High | >999 | >1000 | >963 | >1000 | – | >1000 | >900 |
| D-dimer | | | | | | | |
| Low | – | | – | – | – | – | – |
| High | – | Positive | – | Positive | >0.4 ng/mL | – | – |

CCMB: Croatian Chamber of Medical Biochemists; CLSI: Clinical Laboratory Standards Institute; IFCC: International Federation of Clinical Chemistry and Laboratory Medicine; NASCOLA: North American Specialized Coagulation Laboratory Association.

[a]Mean value from survey responses.

[b]Median value from survey responses

[c]$<20 \times 10^9$/L in patients aged <20 years.

Lippi, et al. Critical laboratory values in hemostasis: toward consensus. 2017. Annals of Medicine, 49:6, 455-461.

# Postanalitik Kalite – Kritik Değerler

**Table 3.** Most frequent causes of critical test results in hemostasis.

**Markedly prolonged APTT**
- Preanalytical error (e.g. wrong sample matrix, sample contamination, inappropriate blood-to-anticoagulant ratio)
- Severe factor XII deficiency (not clinically important)
- Acquired or congenital hemophilia, potentially with inhibitors present
- Patient on anticoagulant therapy (e.g. unfractionated heparin, dabigatran, vitamin K antagonists; including overdosage)
- Disseminated intravascular coagulation (DIC)
- Strong lupus anticoagulant (LA) when using a LA-sensitive reagent

**Markedly prolonged PT**
- Preanalytical error (e.g. wrong sample matrix, sample contamination, inappropriate blood-to-anticoagulant ratio)
- Patient on anticoagulant therapy (e.g. vitamin K antagonists, rivaroxaban; including overdosage)
- Disseminated intravascular coagulation (DIC)
- Liver disease/vitamin K deficiency

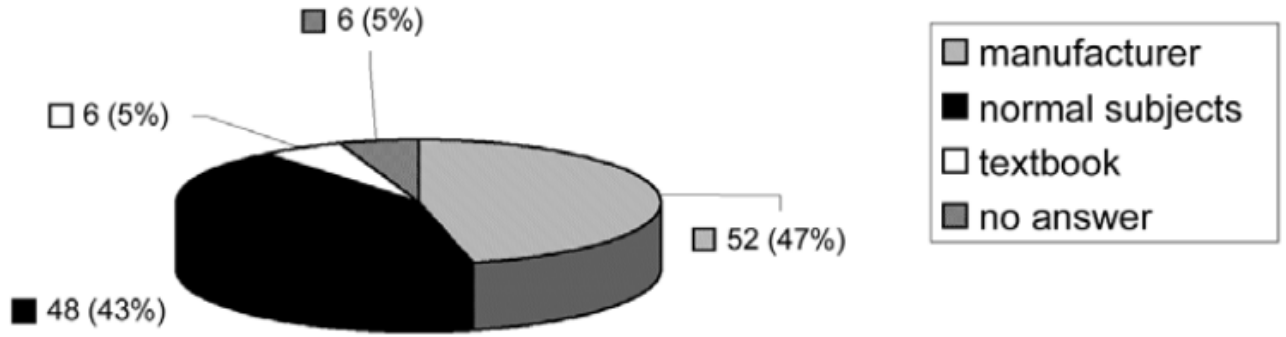
**Markedly decreased fibrinogen**
- Acute liver dysfunction
- Consumption (e.g. disseminated intravascular coagulation; DIC)
- Congenital deficiency of fibrinogen

**Markedly decreased platelet count ("thrombocytopenia")**
- Reduced production (drugs, bone marrow infections, leukemias, other types of cancer)
- Increased consumption (e.g. disseminated intravascular coagulation; DIC; heparin-induced thrombocytopenia; HIT)

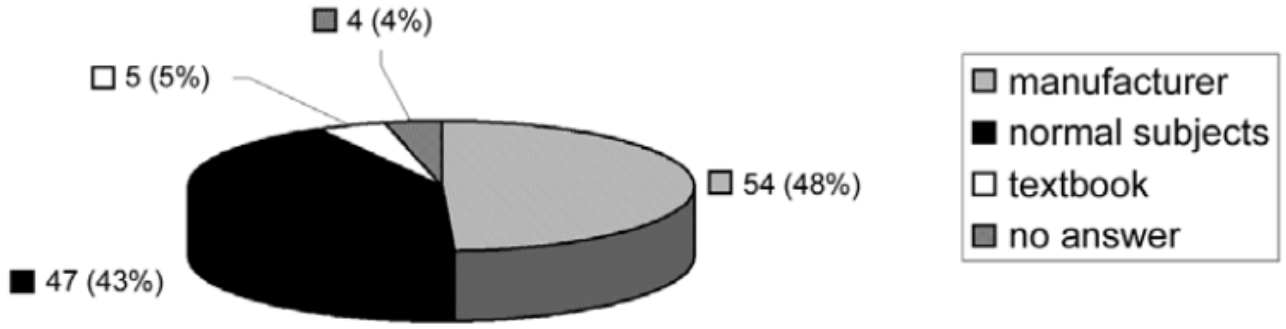
**Markedly increased platelet count ("thrombocytosis")**
- Severe acute infections
- Cancer

Lippi, et al. Critical laboratory values in hemostasis: toward consensus. 2017. Annals of Medicine, 49:6, 455-461.

# Postanalitik Kalite – Referans Aralıklar




(a) PT (n = 112)




(b) APTT (n = 110)

The sources of reference range for PT (a), and APTT (b): laboratories derive reference ranges either from the manufacturer's instructions or from a textbook or establish their own using normal subjects, the percentage of laboratories is shown in bracket

*J Med Assoc Thai Vol. 90 No. 12 2007*

# Postanalitik Kalite – Notlar ve Yorumlar

| Test | Test result | Sample comments |
|---|---|---|
| PT/INR | VKA therapy | Provide therapeutic range. Example: INR ranges suggested for patients stabilized on vitamin K antagonist therapy (e.g., warfarin): prosthetic heart valves, 2.5–3.5; most other indications, 2.0–3.0 |
| APTT | UH therapy | Provide therapeutic range. Example: recommended APTT range for patients on unfractionated heparin therapy: 60–100 s |
| D-dimer | Negative result | A negative d-dimer combined with a structured clinical assessment giving a low pretest probability has a high (>97%) negative predictive value for recent DVT or PE in an outpatient setting |
| D-dimer | Positive result | A positive d-dimer is non-specific and does not establish a recent venous thromboembolism. Although high levels occur immediately after a thrombotic episode, concomitant non-thrombotic conditions (pregnancy, cancer, infections, surgery, trauma) need to be excluded |
| Antithrombin | Low level | Reduced antithrombin level detected. Congenital deficiencies of antithrombin are very rare. Low levels of antithrombin may occur immediately after a thrombotic episode, during heparin therapy, in liver disease, or from a consumptive coagulopathy, hemodilution, and in nephrotic syndrome, following L-asparaginase therapy or a blood collection artifact (including hemolysis). Please exclude these events and repeat the test 1 week after cessation of any anticoagulant therapy |
| Protein C and/ or protein S | Low level | Reduced protein C [and/or S] level detected. Congenital deficiencies of protein C [and/or S] are very rare. Low levels of protein C [and/or S] can occur immediately after a thrombotic episode, with anticoagulant or vitamin K antagonist therapy (e.g., warfarin), vitamin K deficiency or liver disease, on hormone replacement/oral contraceptive therapy/during pregnancy/with nephrotic syndrome [protein S] or from a consumptive coagulopathy, hemodilution, or a blood collection artifact. Please exclude these events and repeat the test 6 weeks after cessation of any anticoagulant therapy |
| Protein C and/ or protein S | Low level—some methods (e.g., some clot-based assays) | [Might need additional comment regarding possibility of interference by APCR or DOACs depending on assay/reagents used] |
| Protein C and/ or protein S | Elevated—clot-based assay | [Might need comment regarding possibility of interference from LA] |

Favaloro, Lippi. Postanalytical IssuesHemostasis and Thrombosis.

# Postanalitik Kalite – Notlar ve Yorumlar

| | | |
|---|---|---|
| Protein S | Elevated—LIA-based assay | [Might need comment regarding possibility of interference from rheumatoid factor] |
| Activated protein C resistance | Any result | Individuals with lupus anticoagulant, factor inhibitors, factor deficiencies, or on anticoagulant therapy [including DOACs] may not provide reliable assay results |
| Lupus anticoagulant test | Prolongation in screen test/mixing study, but unclear correction using confirmatory test | Equivocal test result. If patient is on anticoagulant therapy (vitamin K antagonist, heparin, or DOAC), repeat testing when therapy has ceased. Otherwise, result may indicate presence of another inhibitor (e.g., FV or FVIII); please discuss with laboratory as further testing may be required |
| Lupus anticoagulant test | Positive result | Suggest repeat testing in 12 weeks for confirmation |
| Anticardiolipin antibody | Negative | Some patients with antiphospholipid syndrome have undetectable anticardiolipin antibodies. Lupus anticoagulant testing suggested |
| Anticardiolipin antibody | Low/equivocal/positive | The risk of clinical symptoms in the antiphospholipid syndrome appears to rise with increasing levels of IgG anticardiolipin antibodies. Repeat testing (after 12 weeks) is recommended, as is lupus anticoagulant testing. Transient low level/positive results generally are of questionable clinical significance |
| Anticardiolipin antibody | IgG negative/IgM positive | IgM anticardiolipin antibodies are less specific than IgG anticardiolipin antibodies for the antiphospholipid antibody syndrome. Transient IgM aCL may be found in a range of other inflammatory, infectious, and malignant disorders, and rheumatoid factors may also produce false-positive results. Repeat testing (after 12 weeks) is recommended, as is lupus anticoagulant testing |
| Factor assays | Low levels | [Depending on factor and pattern of test results, consider the possibility of comments and further discriminatory testing related to possible interference with heparin (e.g., low FVIII, IX, XI, and XII) or VKA (low FII, FVII, FIX, FX), DOACs, or testing of EDTA plasma (low FV, FVIII) or serum (low FII, FV, FVIII, FIX, FX)] |

Favaloro, Lippi. Postanalytical IssuesHemostasis and Thrombosis.

# Postanalitik Kalite – Notlar ve Yorumlar

| Test | Test result | Sample comments |
|---|---|---|
| Factor inhibitor | Positive result | [Consider possibility of LA, DOACs, or EDTA or heparin contamination] |
| von Willebrand factor | Pattern suggestive of type 2 VWD (i.e., functional discordance between VWF:Ag and VWF:CB and/or VWF:RCo or loss of high molecular weight VWF multimers) | Results suggestive of type 2 [e.g., 2A or 2B 2M or pseudo-/platelet-type (depending on results)] von Willebrand disease. Further studies may be indicated; please contact laboratory for advice, or else send repeat sample for retesting and confirmation. Please note the following can all provide a false type 2 VWD test pattern: testing of filtered plasma or serum sample or testing of plasma after the refrigeration or storage of whole blood sample at low temperature |
| von Willebrand factor | Pattern suggestive of functional discordance between VWF:Ag and FVIII:C | Results suggestive of [hemophilia A, hemophilia A carrier, acquired deficiency, or type 2N von Willebrand disease (depending on test pattern obtained]). Further studies may be indicated [also consider the possibility that serum was tested] |
| PFA-100 | Prolonged closure time (CT) result with C/Epi, normal with C/ADP | Prolonged closure time (CT) result with C/Epi, normal with C/ADP. Results consistent with any of the following: low platelet count, low hematocrit, recent antiplatelet medication (e.g., aspirin), mild platelet dysfunction, and/or mild von Willebrand disease. Suggest medication review and full blood count. Other studies may be indicated; please discuss with laboratory if required. [Note: comment can be modified as appropriate depending on other test results, e.g., if platelet count and hematocrit are available] |
| PFA-100 | Prolonged closure time (CT) result with both C/Epi and C/ADP | Prolonged closure time (CT) result with both C/Epi and C/ADP. Results consistent with any of the following: very low platelet count, very low hematocrit, recent antiplatelet medication (e.g., aspirin), moderate to severe platelet dysfunction, and/or moderate to severe von Willebrand disease. Suggest medication review and full blood count. Other studies may be indicated; please discuss with laboratory if required. [Note: comment can be modified as appropriate depending on other test results; e.g., if platelet count and hematocrit are available] |
| PFA-100 | Normal closure time (CT) result with both C/Epi and C/ADP | Normal closure time (CT) result with both C/Epi and C/ADP. This result will not always discount a primary hemostasis disorder. If patient being investigated for mucocutaneous bleeding, please discuss with laboratory, as further testing may be required |

Favaloro, Lippi. Postanalytical IssuesHemostasis and Thrombosis.

# Postanalitik Kalite – Notlar ve Yorumlar

| | | |
|---|---|---|
| LMWH | Anti-Xa level | Monitoring of LMWH is rarely required, except in renal failure, extreme of body weight, or situations in which there is an increased risk of bleeding. Heparin assay performed using an anti-Xa procedure using a commercial calibrant [name drug] for the standard curve. Test results for different LMWH drugs may give slight differences in activity levels. Test results for patients on anticoagulants other than LMWH drugs will not be meaningful. Current therapeutic interval used for patients of [name institution]: 0.5–1.2 U/ml at 3–5 h after last dose |
| Dabigatran | Dilute TT | Dabigatran does not require routine monitoring, and this test is not to be used for dosage adjustments. Dabigatran assay performed as an antithrombin procedure and a commercial reference plasma for the standard curve. Test results for patients on anticoagulants other than dabigatran will not be meaningful. There is no widely accepted or validated therapeutic interval for dabigatran, and levels vary widely from patient to patient and also depend on time of last dosage. Anticipated range of level for patients receiving dabigatran would be approximately 40–450 ng/ml |
| Rivaroxaban/ apixaban | Anti-Xa level | Rivaroxaban[/apixaban] does not require routine monitoring, and this test is not to be used for dosage adjustments. Rivaroxaban[/apixaban] assay performed as an anti-Xa procedure using a commercial reference plasma for the standard curve. Test results for patients on anticoagulants other than rivaroxaban[/apixaban] will not be meaningful. There is no widely accepted or validated therapeutic interval for rivaroxaban[/apixaban]. Levels of rivaroxaban[/apixaban] vary widely from patient to patient and also depend on time of last dosage. Anticipated range of level for patients receiving rivaroxaban[/apixaban] would be approximately 40–400 ng/ml [/40–250 ng/ml] |
| All tests performed by latex immunoassay | Elevated | [Might need comment regarding possibility of interference from rheumatoid factor] |
| Any test | Additional add-on comment to any of the above comments | Please discuss with/contact the laboratory/hematologist for further advice |

Favaloro, Lippi. Postanalytical IssuesHemostasis and Thrombosis.

# Koagülasyon Testlerinde Genel Sorunlar

| |
|---|
| Poor knowledge of hemostasis in health and disease |
| Heterogeneity of available guidelines for diagnosis and therapeutic management |
| Inaccurate definition of reference ranges |
| Identification and communication of critical values |
| Harmonization of preanalytical, analytical and postanalytical procedures |

# Kalite için gereken yol göstericiler

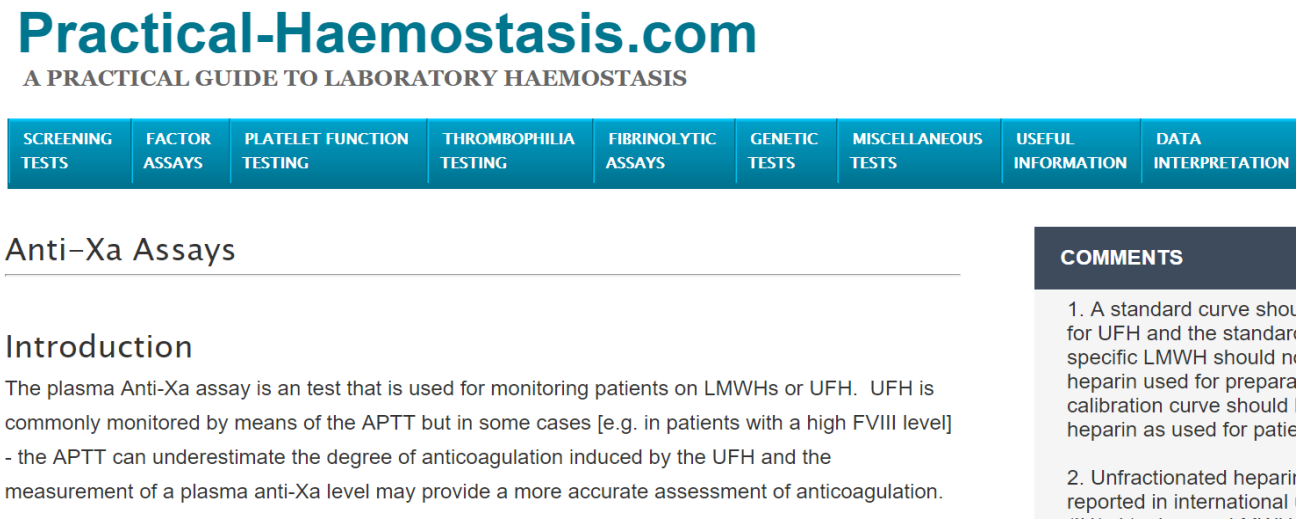
- CLSI (Clinical and Laboratory Standards Institute)
- BSH (British Society of Hematology)
- ISLH (International Society of Laboratory Hematology)
- ICSH (International Council on Standardization in Hematology)

# Sürekli eğitim

ISLH
INTERNATIONAL SOCIETY FOR LABORATORY HEMATOLOGY

**islh.org**

**practical-haemostasis.com**




Quality