Babesiosis

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Presentation Overview

• Background information
• Risk of transmission
• Babesia Guidance (FDA)
• Babesia donor testing strategy
Background Information

- Human babesiosis is a tick-borne zoonosis from the genus *Babesia*
- It is also transmitted by transfusion of blood and blood components, and transplantation of solid organs
- Highest prevalence is in the United States
- First documented case of human babesiosis in the U.S. was in 1968
- Most U.S. cases caused by *B. microti*, prevalent in the Northeast and upper Midwest
Risk of Transmission

• Most infections are asymptomatic and never diagnosed

• Parasitemic period lasts from 2-7 months, but parasitemia may persist for more than 2 years.

• In a study of asymptomatic donors, follow up testing demonstrated DNA clearance in 86% after 1 year, and 95% after 2 years.

• Generally seasonal and coincides with tick activity (May-September) in affected states

• Transfusion from asymptomatic donors may result in potential fatal clinical illness

• In tick-borne cases, fatality ranges from 6-9% among hospitalized patients and up to 21% in immunosuppressed patients

• FDA classified as “TTI” transfusion transmitted infection and “RTTI” relevant transfusion transmitted infection under 21 CFR 630.3
FDA Guidance for Industry

• Finalizes the FDA draft guidance document dated July 2018
• Appropriate screening measures include:
  – Licensed NAT Screening Test - Grifols Procleix Babesia Assay
  – Pathogen Reduction - FDA has approved pathogen reduction devices that report effective reduction of *B. microti* for indicated plasma or platelet components
FDA Guidance for Industry

- Universal testing year-round required for collections in the following States and the District of Columbia:
Blood Supply Safety: FDA Conclusions

Blood establishments to implement nucleic acid testing of all donations or pathogen reduction technology to reduce the risk of Babesia transmission.

Key provisions of the final guidance are:

• Test all donations collected in identified states using a licensed NAT assay
• Defer any donors with a reactive Babesia NAT result for 2 years
Blood Supply Safety: FDA Conclusions

Key provisions, continued:

- Alternatively, implement pathogen reduction for platelets and plasma
- Whole blood or red blood cells may be pathogen reduced when technologies become available
- If testing or using pathogen reduction, *Babesia* related questions are not recommended on the donor questionnaire*

Blood centers should review the guidance for further information on DHQ revision, product management, product labeling, and Circular of Information
Blood Supply Safety: FDA Conclusions

Donors Previously Deferred

- Donors previously deferred for a history of babesiosis or a positive Babesia test result may be eligible to donate provided the following conditions are met:
  
  - On the day of donation, the donor has not had a positive test for Babesia in the last two years, and meets all other eligibility requirements
  
  - The donation must be tested for Babesia by a licensed NAT and found to be nonreactive at the time of collection
Babesia testing strategy
**Babesia Testing**

- CTS will implement the Grifols Procleix *Babesia* assay beginning with samples received on April 20, 2020

- *Babesia* must be added to your donor panel and validated with IT.
  - Blood center IT personnel must contact CTS IT
    - Subhash Parameswaran
      [Sparameswaran@mycts.org](mailto:Sparameswaran@mycts.org)
      602-343-7168
    - Pauline
      [PRoesler@mycts.org](mailto:PRoesler@mycts.org)
      602-343-7198

- Requires collection of an additional purple top EDTA tube
Babesia Testing

Two methods of ordering Babesia testing:

- **Babesia** can be ordered on the CTS website

- Clients can use the FTP process to order
  - This option requires additional validation with CTS IT
New Packing Requirements

Adding the additional EDTA tube to the sample shipper:

Extra purple top should be placed immediately behind the other purple top tube in the white tube box
Supplemental Testing for Positive Donations

- Approved by the CTS Medical Advisory Board
- *Babesia* reactive donations will be tested with the Grifols Procleix *Babesia* assay on the alternate purple top tube
- Result will be provided in the same manner as your other confirmatory results
Requalification of donors

- Two year deferral period is required before you can re-enter a donor with a previous positive Babesia test.
- Two methods available for re-entering donors:
  - Send four sample tubes to receive all testing including Babesia
  - Complete a 173 form for Babesia only and send to CTS Special Testing Laboratory in Phoenix
# MISCELLANEOUS REQUEST FORM

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### PROFILES

- [ ] Include confirmatory testing, if applicable, for the Profile marked below
- [ ] PROFILE A: (HBsAg, HCV, HIV 1/2)
- [ ] PROFILE B: (HBsAg, HCV HIV 1/2, HTLV I/II)
- [ ] PROFILE C: (HBsAg, HbC, HCV, HIV 1/2, HTLV I/II)
- [ ] PROFILE D: (HBsAg, HbC, HCV, HIV/HCV/HBV NAT IDS, HIV 1/2, HTLV I/II)
- [ ] PROFILE E: (HBsAg, HbC, HCV, HIV/HCV/HBV NAT IDS, HIV 1/2, HTLV I/II, Syphilis Screen MHA-TP)
- [ ] PROFILE F: (HBsAg, HbC, HCV, HIV/HCV/HTLV NAT IDS, HIV 1/2, HTLV I/II)
- [ ] PROFILE G: (HBsAg, HbC, HCV, HIV/HCV/HTLV NAT IDS, WNV NAT IDS, HIV 1/2, HTLV I/II)
- [ ] PROFILE H: (HBsAg, HbC, HCV, HIV/HCV/HTLV NAT IDS, WNV NAT IDS, HIV 1/2, HTLV I/II, Syphilis Screen MHA-TP, CMV, ABO/Rh, T. cruzi)

### NAT TESTING

- [ ] HIV/ HCV/ HBV NAT (IDS)
- [ ] dHIV NAT
- [ ] dHCV NAT
- [ ] dHBV NAT
- [ ] WNV NAT (IDS)
- [ ] Babesia
- [ ] ZIKA

### INDIVIDUAL SCREENING TESTS

- [ ] Include confirmatory testing, if applicable, for any tests marked below
- [ ] HBc (Ortho)
- [ ] HBsAg (Genetic Systems)
- [ ] HCV (Ortho)
- [ ] HIV½ + O (Genetic Systems)
- [ ] HTLV I/II (Avioq)
- [ ] T. cruzi (Abbott)
- [ ] ABO/Rh only
- [ ] Antibody Screen
- [ ] Antibody ID, if POS
- [ ] CMV
- [ ] HBs antibody
- [ ] HLA
- [ ] Babesia
- [ ] Other (Specify): 

### CONFIRMATION

- [ ] HCV
- [ ] Ortho
- [ ] HIV-1 W
- [ ] If NE
- [ ] HIV-2 EL
- [ ] If RE
- [ ] Geenius
- [ ] HTLV-I/II
- [ ] Syphilis
- [ ] If react
- [ ] T. cruzi
- [ ] WNV IgG
- [ ] Other (Specify): 

Sample received at CTS CLT/DAL/PDX/STL/TPA:
- [ ] Refrigerated
- [ ] Frozen
- [ ] Ambient

Initials: Date: Time: Sample:

**CTS Phoenix Use Only**
Client Action Items

- Review the Guidance Document
- Work with CTS IT to complete validation
- Review the packing configuration for four tubes
- Implement the revised 173 form on April 20, 2020
- Notify your Customer Service Manager (CSM) of your intended implementation date
Questions?

For additional information on *Babesia* use the CDC website at
https://www.cdc.gov/parasites/babesiosis/index.html