Welcome to this PACE Self Study Program on Testing Blood Donors for Chagas Disease.
My name is Marie Holub and I will be your presenter today. I am the Education Coordinator for Blood Systems Laboratories. I have given this presentation for a live audience as well as for web delivery.

I have a master in education and currently teach in the on-line Blood Bank Technology Program. I also teach a face-to-face class in Immunology and Immunohematology for a community college in Arizona. I have worked for Blood Systems for 16 years during this time I have worked in the IHS laboratory and Corporate Office. I have also worked as the supervisor of hospital based transfusion services. Education has been important to me throughout my career.
Objectives

At the completion of this presentation participants will be able to:

1. Discuss the epidemiology of Chagas disease
2. Explain the risk to the US blood supply
3. Know how screening strategies differ
4. State the argument for screening the US blood supply for T. cruzi

The information being presented today will cover:

• the epidemiology of Chagas disease
• the risk of transfusion transmitted Chagas disease in the US blood supply
• the different screening strategies for Chagas disease
• and the argument for screening the US blood supply for T. cruzi

The presence of T. cruzi in the blood supply presents a danger to patients requiring transfusion.
After participating in the presentation, we expect you to be able to:

- discuss the epidemiology of Chagas disease
- explain the risk of transfusion-transmitted Chagas disease in the US blood supply
- discuss the differences in screening strategies and
- understand the argument for implementing screening for T. cruzi.

Implementation of testing for Chagas disease in one additional way to keep our blood supply as safe as possible.
Trypanosoma cruzi is the etiological agent of Chagas disease. Humans are infected by a bite of the reduviid bug, one of which is Triatoma infestans. These bugs live in rural dwellings and outbuildings made of mud, adobe and thatch. The reduviid bug becomes infected when it bites an infected animal or human. The social and medical impact of this disease is considerable. It is estimated that about 752,000 working hours are lost per year due to deaths caused by Chagas disease in the seven most southern countries of South America. The medical costs in Brazil for people developing severe cardiac or digestive disease could reach 250 million dollars.

Information from:
Wikipedia
Epidemiology of Chagas Disease from http://www.dbbm.fiocruz.br/tripical/chagas/chapter4/html
Chagas disease was named for Carlos Chagas, who first described it in 1909. Carlos Chagas was a Brazilian physician and infectologist who originally dedicated his initial efforts to the control of malaria. As you can see, this disease has been around for long time. Trypanosomiasis was not considered a major public health problem until the 1960s. The work Dr. Chagas performed with T. cruzi is unique because he was the only researcher to completely describe a new infectious disease. This included the pathogen, vector, host, clinical manifestations and epidemiology. However, Dr. Chagas believed that people were infected by the bite not by the reduvid feces. Another interesting fact is that the parasite was named in honor or Oswaldo Cruz, hence T. cruzi. Oswaldo Cruz was the founder of the Manguinhos Institute, which is now named Institute Oswaldo Cruz, which is responsible for major contributions for the development of Preventive and Sanitary Medicine in Brazil.

For much of his adult life Charles Darwin's illness repeatedly affected him with an uncommon combination of symptoms, leaving him severely debilitated for long periods of time, incapable of normal life and intellectual production, staying in bed most of the time for months. Charles Darwin wrote that "Constant attacks....makes life an intolerable bother and stops all work".

He consulted with more than 20 doctors, but with the medical science of the time the cause remained undiagnosed. He tried all available treatments, but at best they had only temporary success. More recently, there has been much speculation as to the nature of his illness.

Darwin himself wrote of his illness, emphasizing that it was brought on by 'excitement': Few persons can have lived a more retired life than we have done. Besides short visits to the houses of relations, and occasionally to the seaside or elsewhere, we have gone nowhere. During the first part of our residence we went a little into society, and received a few friends here; but my health almost always suffered from the excitement, violent shivering and vomiting attacks being thus brought on. I have therefore been compelled for many years to give up all dinner-parties; and this has been somewhat of a
The possibility of transmitting chagas disease by transfusion was first raised by Mazza in 1936. It is interesting that the Argentine Sanitary code stated that donors who “could suffer from syphilis, recurrent fever, infectious jaundice, tuberculosis, leprosy, Nicholas-Favre, malaria, leishmaniasis, trypanosomiasis or any other diseases whose agent lives or circulates in the bloodstream should be rejected.” This recommendation was made in the 1940’s.

The first cast of transfusion transmitted Chagas disease was reported in 1952. Pedreira de Freitas, who reported the transmission of T. cruzi by transfusion, stated to work on chemoprophylaxis of whole blood the same year. This led nussenzweig to describe the use of gentian violet as a useful agent to inactivate the parasite in 1953.

Information from
Historical Aspects http://www.dbbm.fiocruz.br/tropical/chagas/chapter.html
The acute state of infection occurs in about 1% of people infected with T. cruzi. It is believed that the symptoms are caused by the direct destruction of host cells. The incubation lasts from 7-10 days and is asymptomatic. The symptoms experienced include:

- chagoma - A chagoma is a nodular swelling that develops at the site of parasite entry. The swelling is due to infiltrates of macrophages surrounded by lymphocytes, eosinophils and polymorphonuclear neutrophils. This is an example of an acute local inflammatory reaction.
- swelling of the eye
- tiredness
- fever
- rash
- loss of appetite
- lymphadenopathy
- hepatosplenomegaly
- myocarditis

The heart is the main target during the acute phase. About 10-20% of acute cases resolve over a period of 2-3 months into an asymptomatic chronic phase. However, the symptoms may reappear after several years. These symptoms are more severe in younger patients and may be fatal, especially in children younger than 2 years.
This is an example of preorbital edema. This symptom is also known as Romana sign and is typically present in 20-50% of acute cases. Although this symptom looks painful, it is painless and frequently accompanied by conjunctivitis and local lymph node enlargement. This condition can persist for 30-60 days.

Information from eMedicine
eMedicine http://www.emedicine.com/med/topic327.htm
<table>
<thead>
<tr>
<th>Stage</th>
<th>Duration</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermediate</td>
<td>8 to 10 weeks after infection</td>
<td>No symptoms</td>
</tr>
<tr>
<td>Chronic</td>
<td>10 to 20 years after infection</td>
<td>Enlarged heart and digestive tract, can result in heart failure, severe constipation or problems with swallowing, little effective therapy (toxic drugs/low cure rates)</td>
</tr>
</tbody>
</table>

Following the acute phase, the intermediate phase is usually associated with no symptoms and may resolve into an asymptomatic chronic phase. However, a symptomatic chronic phase may appear in which the disease affects the nervous system, digestive system and heart. Treatment during the chronic phase usually involves managing the clinical manifestations of the disease.

Information from Wikipedia
As indicated on this slide, clinical manifestations of the disease may not appear for years or decades after infection. Individuals may experience neurological effects such as dementia, damage to the heart muscle and dilation of the digestive tract. Difficulty swallowing may be the first sign of digestive problems and may also lead to malnutrition. Death is usually caused by cardiac complications. Treatment for symptomatic chronic disease is usually managing the clinical manifestations such as a heart pacemaker or surgery for megacolon. However, the disease is usually not curable at this stage.

Information from Wikipedia
These films show examples of the damage caused by trypanosomiasis to the heart muscle. This represents cardiomyopathy. The heart experiences biventricular failure with peripheral edema. Other physical changes include hepatomegaly and pulmonary congestion at the later stages of infection.

Information from eMedicine
http://www.emedicine.com/med/topic327.htm
These photos show the parasite located in heart muscle. The parasite is in the amastigote phase. This phase is the intracellular replicative form of the parasite. The parasite is in a spherical form devoid of free flagellum that cannot move.

Information from eMedicine http://www.emedicine.com/med/topic327.htm
One of the best and simplest ways to diagnose Chagas disease is to perform a microscopic examination of a drop of fresh anticoagulated blood at 400x magnification. One can observe the rapid movements of live T. cruzi trypomastigotes. To conclude that the parasite is not present, at least 100 fields should be examined.

The xenodiagnostic method is performed by feeding 40 laboratory-reared and uninfected reduviid bugs with blood from the patient. The insects can be put directly on the skin or can be exposed to anticoagulated blood through a thin latex membrane. After 30-60 days, the intestinal contents of the insects are examined for metacyclic trypomastigotes.

The parasite may be cultured from the blood on liver infusion typtose medium maintained at 28°C. However, this test takes even longer than the xenodiagnostic method since the culture is observed monthly for 4-6 months.

One final method is inoculate animals with a sample from a suspected patient and then observe the animal for subsequent infection. This method is no longer in use.

Information from eMedicine http://www.emedicine.com/med/topic327.htm
This slide shows a blood smear with typomastigotes. This stage of the flagellate parasite does not divide. The kinetoplast is an organelle with unique and large mitochondrial containing the extranuclear DNA. The flagellum originates from the kinetosome adjacent to the kinetoplast and runs alongside the body of the parasite. The flagellum may adhere to the body of the parasite in some points and is responsible for the considerable motility of the elongated trypomastigote.

Information from eMedicine http://www.emedicine.com/med/topic327.htm
Chagas’ Disease

Geographic Distribution

- South America (except Guyana, French Guyana and Suriname)
- All of Central America
- Part of Mexico
- 18 million people infected
- 1-2 million in large, non-endemic areas (Sao Paulo, Rio, Buenos Aires)
- 100,000 in the U.S. (?)

This disease is known as American trypanosomiasis since the parasite is found only in the continental Americas including Central and South America. T. cruzi has rarely been reported to cause natural infection in the United States. However, this parasite is becoming more prevalent due to the immigration of infected people from endemic areas into the US and Canada. It is estimated that 16 to 18 million people are infected and possibly up to 100 million people are at risk of becoming infected. Approximately 50,000 people die each year from American trypanosomiasis. These figures vary depending upon the source of information. The number of infected people living in the US is estimated to be 100,000 and could be as high as 500,000.

Information from Wikipedia
Where is Chagas Disease Found?

- Primarily found in Latin America
- Increased infections are being detected in the United States

This map is representative of the endemic areas. There are differences between the infectivity rate in different countries. About 20% of the Bolivian population is infected compared to 1.3% of the Brazilian population. Argentina, Honduras, Paraguay and El Salvador have an estimated 5-10% of the population infected. 1-5% of the population of Chile, Columbia, Ecuador, Uruguay and Venezuela are estimated to be infected and less than 1% of the people in Mexico and Nicaragua are expected to be infected.

Information from
eMedicine http://www.emedicine.com/med/topic327.htm
This disease is obviously more prevalent in Hispanic origin persons. The darker areas on the map represent a larger number of donors at risk for Chagas disease in the US. It is not surprising that the higher risk areas are in the Southwestern regions of the country.
There are over 100 species of reduviidae. These insects may be difficult to identify because their appearance varies greatly among genera. Reduviid bugs are from one to three centimeters in length and are good fliers. Various species of the reduviid bug are capable of carrying the trypanosome parasite which are indicated on this slide. This insect is called the kissing bug because it often bites people on the face. People that live in huts with mud walls and thatched roofs are more likely to be bitten and infected.

Information from Kissing Bugs in the Americas Final
http://jrscience.wcp.muohio.edu/fieldcourses04/PapersCostaRicaArticles/KissingBugsInTheAmericasF.html
The face and arms are most likely to be exposed while sleeping. The reduviid bug bites a person and then defecates. The feces contain metacyclic forms of the parasite. The metacyclic trypomastigotes are more infective than blood trypomastigotes. Most people tend to scratch the bite location which spreads the parasite into the wound or conjunctiva. T. cruzi can easily penetrate mucosa through the mouth, nose or eye. The parasite cannot seem to penetrate normal, unbroken skin with the exception of very young children.

Chagas disease may be treated during the incubation period and beginning of the acute phase. This treatment uses benznidazole, bed rest and antithermic and analgesic drugs.

Information from
eMedicine http://www.emedicine.com/med/topic327.htm
Epidemiology of Chagas Disease http://www.dbbm.fiocruz.br/tropical/chagas/chapter4.html
Reduviid bugs are often found in poorer neighborhoods. Houses made of mud, adobe and palm leaves provide more places for the bug to hide during the day. The insects are more active at night during which time they can feed on humans. Infection rates vary between villages. The infection rate in Costa Rica is about 35 percent while the infection rate in South American homes can range from 38 to 96 percent.

Information from Kissing Bugs in the Americas Final http://jrscience.wcp.muohio.edu/fieldcourses04/PapersCostaRicaArticles/KissingBugsintheAmericasF.html
This is an example of the Reduviid bug in a dwelling. Please note the red circle that helps you locate the bug. Colonies of hundreds or thousand of bugs can be found in these dwellings. Only a few species of reduviid bugs are vectors for T.cruzi. Many species are strictly inhabitants of the wild and never invade houses. These kissing bugs pose no threat to humans.

Information from Epidemiology of Chagas Disease
http://www.dbbm.fiocruz.br/tropical/chagas/chapter4.html
The life cycle of Trypanosoma cruzi begins with the reduviid bug biting an infected animal or human and becoming infected with T. cruzi. The kissing bug then bites another person, usually on the face, and releases the trypomastigotes in its feces near the site of the bite wound. The trypomastigotes enter through the wound or through intact mucosal membranes, such as the conjunctiva. The trypomastigotes invade cells near the site of inoculation and differentiate into intracellular amastigotes. Here they multiply by binary fission and differentiate into trypomastigotes which are released into circulation as bloodstream trypomastigotes. Cells from a variety of tissues are infected and the trypomastigotes transform into intracellular amastigotes at the new infection sites. Clinical manifestations may result from this infective cycle. In contrast to African trypanosomiasis, the bloodstream trypomastigotes do not replicate. Replication only occurs when the parasite enters another cell or are ingested by another kissing bug. The parasites transform into epimastigotes and multiply and differentiate in the midgut of the reduviid bug.

T. Cruzi can also be transmitted through organ transplantation, transplacentally from mother to child and through transfusion.

Information from CDC http://www.cdc.gov/ncidod/dpd/parasites/chagasdisease/index.htm
Only mammals can be infected with T. cruzi. Birds, frogs and lizards are naturally resistant to infection. Pigs, goats, cattle and horses do not play an important role in the domestic cycle since they manifest only transitory parasitemia. There are 150 species that may be animal reservoirs for T. cruzi in the sylvatic cycle.

Information from eMedicine http://www.emedicine.com/med/topic327.htm
The domestic cycle involves T. cruzi transmission to humans. Only 7-8 species of Reduviid bugs are capable of transmitting Chagas disease. These vectors are responsible for 80% of human infections. The animals frequently infected in the domestic cycle include: dogs, cats, mice, rats, guinea pigs, and rabbits. Interestingly, chickens are an important source of blood meals, but remain uninfected. Transmission of T. cruzi through blood transfusion is discussed later in this presentation.

Congenital transmission occurs in about 2-10% of infants born of infected mothers. T. cruzi may be transmitted during both the acute and chronic stages of the disease. It is extremely rare for the parasite to be transmitted through breast milk.

Oral transmission is due to the ingestion of food contaminated by reduviid bug feces; however, this mode of transmission appears to be more frequent in settlers of Amazonian areas.

Information from Chagas Disease (American Trypanosomiasis) in eMedicine
http://www.emedicine.com/med/topic327.htm
An incident or oral transmission was reported in southern Brazil in March 2005. The raw sugar cane was contaminated with feces from infected bugs. There were 25 cases of confirmed acute Chagas disease which resulted in 6 deaths.
The etiological agent of Chagas’ disease is the intracellular protozoan parasite *Trypanosoma cruzi* (*T. cruzi*), which is transmitted by the insect vector *Triatoma infestans*?

True

Please click your mouse or press the page down key to display the correct answer. The three most important reduviid species that may transmit *T. cruzi* include:

- *Triatoma infestans*
- *Rodnius prolixus*
- *Triatoma dimidiata*

*T. infestans* is found in countries south of the Amazonian basin and is responsible for more than half of the infections. *R. prolixus* is found in Central America and countries north of the Amazonian basin. *T. dimidiata* is found in Columbia, Ecuador, all along the Pacific coast and from north Peru into Mexico.

So, why should we screen donors for Chagas disease? Since many infected individuals are asymptomatic, blood donors with Chagas disease may not be aware that they are infected. The FDA sought advise from the Blood Products Advisory Committee or BPAC on issues related to recommendations for implementation of blood donor screening for Chagas disease. The are currently no FDA recommendations on implementation of donor screening for Chagas disease. The FDA did share the AABB Association Bulletin 06-08 providing the following recommendations for facilities implementing an FDA-licensed Chagas’ screening test:

- We should quarantine blood components, including prior in-date components and perform consignee notification
- Look-back should be initiated with a positive test and recipient testing performed
- Components from autologous donor with repeat-reactive test results should be released for use
- Deferred donors should be notified and confirmatory results given to the donor
- Donor should be referred for medical evaluation.

Information from BPAC meeting 4/26-4/27/07

- T. cruzi aby demonstrate in US blood donors in multiple geographic locations (estimated rate of 1:30,000 nationally)
  - Los Angeles 1:550........(Shulman et. al)
  - US 1:25,000 estimate......(Dr Vostal)
  - 63% of positive donors are Parasitemic...(Red Cross)
  - 7 cases so far...how many are missed? (Dr Vostal)
  - Serious morbidity/mortality for recipients

BPAC minutes, August 7th 2002

This information has been presented to BPAC. Prevalence of donors with antibody to T. cruzi is estimated to be one in 30,000 worldwide. Shulman reported the prevalence rate to be approximately one in 550 in Los Angeles. Red Cross testing has found that 63% of the donors with antibody to T. cruzi also have parasitemia. Since many patients receiving blood transfusion are ill, transfusion transmitted Chagas disease can have serious morbidity and mortality.
It is estimated that over 12 million people have immigrated from Mexico, Central and South America. The 2000 census indicated that the number of Hispanic individuals was up nearly 60% from the 1990 census. Population demographics now indicate that the number of Hispanic origin people is roughly equal to the number of African American individuals.
Why Is Chagas Testing Needed For The U.S. Blood Supply?

Estimated Risk of Transmission of T. cruzi in the United States

13.2 million donations/year

618 potentially infectious components/year

Reference Source: Dr. D. Leiby, American Red Cross

Based on the estimated rates of donor infections, we could conceivably transfuse over 600 potentially infectious components per year. It is estimated that the transfusion of infected components that contain trypomastigotes is responsible for 5-20% of the human cases of Chagas disease.

Information from eMedicine http://www.emedicine.com/med/topic327.htm
There have been seven known cases of transfusion transmitted Chagas disease in the US and Canada. Platelet transfusion was implicated in six of the seven cases. The implicated blood component was not identified in the seventh case.

Information from Blood Banking and Transfusion Medicine page 657.
The recipients developed symptoms approximately two to three months after transfusion. In six of the cases, the donor emigrated from an endemic area including Bolivia, Mexico, Paraguay and Chile. Four of these donors had emigrated between 16 and 33 years before donating the implicated units. Hopefully, transfusion transmission of T. cruzi is inefficient due to the small number of reported cases.

Information from Blood Banking and Transfusion Medicine page 657.
T. cruzi positive units collected in endemic areas have an estimated transfusion-transmission rate of 13 to 26%.

35 recipients tested in look-back studies did not show any transfusion transmission of T.cruzi.

It is possible that centrifugation may sediment the parasite in the platelet rich plasma during Whole Blood derived Platelet component production. Room temperature storage of platelets may also favor the survival to T. cruzi.

However, T. cruzi has also been shown to survive in red cell components for up to three weeks.

Plasma does not pose a risk for transmission of Chagas disease.

Information from Blood Banking and Transfusion Medicine page 657.
A single cadaveric donor was responsible for the infection of three organ recipients. One recipient received a kidney and pancreas, one received a kidney and the third received the liver. All of the recipients cultured positive for T. cruzi.

Information from AABB Audioconference: Why Donor/Patient Counseling is Needed for Chagas, 01/27/07.
The recipient of the kidney and pancreas transplants got her organs on March 5th. More than a month later, she showed signs of a febrile illness. The parasite was identified on a peripheral blood smear less than a week later.
First U.S. Transplant Cases cont.

- Two other persons received organs from the same donor
  - A woman aged 32 years received the liver
  - A woman aged 69 years received the other kidney
  - Both found to be infected with *T. cruzi*

*Source: MMWR March 15, 2002 / 51(10):210-2*

The other two recipients of organs from the infected cadaveric donor were also found to be infected with *T. cruzi.*
The cultures performed on all three recipients were positive for T. cruzi. The organ donor was an immigrant from Central America and length of time the donor was living in the US is not known for this presentation. Unfortunately, there were no specimens from the donor to be tested for T. cruzi or antibodies to T. cruzi.
Chagas Disease Quiz

Multiple Choice

2. How many cases of transfusion transmitted Chagas disease have been reported in the US?

   a. 2
   b. 5
   c. 7
   d. 26

Please click your mouse or press the page down key to display the correct answer. And the correct answer is 7. Donors are questioned about geographic location of birth, extended stays or transfusion in areas endemic for Chagas disease to reduce the risk of the transmission of T. cruzi. These questions may only be 75% effective in preventing transfusion transmission of Chagas disease. Leukocyte filtration may reduce T. cruzi transmission by 50-70% in a mouse transfusion model. Continue on to learn about seroprevalence and testing options.

Information from Blood Banking and Transfusion Medicine page 658.
The results of seroprevalence studies are indicated on this slide. Donors responding yes to a risk question were tested. Both Los Angeles and Miami have a large Hispanic origin population. As you can see, less than one percent of the donors were confirmed positive for T. cruzi infection.
This slide indicates the increase of seropositive donors from one in approximately 9900 in 1996 to one in approximately 5400 in 1998.
Recent US Chagas Testing

- Ortho expanded 2006 clinical studies to include areas where T. cruzi antibody prevalence was previously documented.
  - Pivotal Clinical Trial yielded 0 confirmed positive of 40,665.
  - Previous preclinical study: 3 in 10,000 in El Paso.
  - Additional testing for donors fromSo Cal, No Cal, and AZ (West ARC Division).
  - Over 100,000 donations tested with reactive rate 1:2,500.
  - Unlinked prevalence test results pending.

In 2006, the Ortho clinical studies were expanded to include areas where T. cruzi had been previously documented. Arizona and southern and northern California were included and over 100,000 donors were tested. The reactive rate increased to one in approximately 2500.
A demonstrated by this slide, the prevalence of T. cruzi in the donor population has increased from approximately one in 9000 in 1996 to one in 2500 in 2006.
Please click your mouse or press the page down key to display the correct answer. I am sure that you chose false as the correct answer. The reasons for an increase in the seropositive rate is due to immigration of people from endemic areas. As previously mentioned, it is estimated that over 12 million people from Mexico, Central and South America have immigrated.
In 2002, Dr. Nakashi from the FDA stated that when a good test comes along, it will be recommended.
Implementing any new test incurs additional cost and raises many questions. Some issues to be addressed in testing for Chagas disease include whether to perform universal or selective testing. If we choose selective testing, do we select by geographical regions, test the donor only once or select by ethnicity or the country from which the donor immigrated.

We have to consider whether to perform confirmatory testing or test with a second screening test when available. What will be the guidelines for developing a look-back policy? How will this affect public health labs? Will public health departments need to be notified? I do not have answers to these questions.
Universal screening generally means testing each donation. The advantages would include minimizing the risk of missing a real carrier. Since every donation is tested, the sensitivity of testing is increased.

Disadvantages would obviously include the cost of testing. Repeat reactive ELISA results would need to be confirmed. Donors would be deferred since this is a lifelong infection and because of this donors would need notification. This then raises the issue of donor counseling regarding the clinical significance of infection by T. cruzi.
Selective testing would definitely decrease the cost of testing. Since fewer donors are tested, there would also be fewer donors that would need to be deferred.

The disadvantage would be missing donors that have been infected that are not immigrants into the US. This would include cases from individuals that have traveled to an endemic area and congenital transmission.

Another issue that will impact donor centers and blood donor testing laboratories is making sure that the correct tube is tested. This can be a logistical nightmare.
Problems with Selective Screening


"Testing of only 1st time donors, while an attractive idea, would likely increase testing errors and would be problematic in the case of donors who travel to endemic areas...Strategies designed to assess risk, either for deferral or selective testing have been shown to lack sensitivity"

As indicated by Leiby, the sensitivity of the testing is decreased with selective screening. (pause for 10 seconds to allow participants to read slide)
One screening strategy would be to perform universal screening for two to three years. Based on the data collected during this period, the strategy could be modified to support a selective testing strategy. Aliquots from samples that test positive should be frozen. These samples may be used for validation of another manufacturer’s assay for Chagas disease.

This strategy would give the blood banking industry time to create algorithms supporting testing of first time and travel donors.
4. Selective donor screening makes sense in that the likelihood of transmission occurs in specific geographic regions?

True

Please click your mouse or press the page down key to display the correct answer.

Remember that there are cons to this screening strategy. Vermont is the only state that has not had a repeat reactive Chagas test. This information is available on the AABB Chagas’ Biovigilance network. You can find this on the AABB Website under Program and Services then Data and Special Programs. This site includes the location of confirmed RIPA positive donations and repeat reactive test result numbers.
One confirmatory test for Chagas disease is radioimmunoprecipitation assay or RIPA. This test is performed using a radiolabeled antigen, T. cruzi, which is allowed to react with the corresponding antibody. The antigen-antibody complex is then precipitated. The precipitated immunocomplex is then analyzed by gel electrophoresis.

This procedure was compared to indirect immunofluorescence assay, indirect hemagglutination assay and ELISA assays. RIPA compared favorably with the methods previously listed.

Informaton from Radioimmunoprecipitation Assay
http://www.websters-online-dictionary.org/Ra/Radioimmunoprecipitation%20Assay.html
RIPA is extensively used in research testing and is highly sensitive and specific. This test is performed in reputable labs.
Please press the page down key to display the cons for RIPA.

The disadvantage of using the RIPA assay is the need to send samples out for testing. RIPA is a complex test that takes a long time to perform thereby increasing the turn-around-time for results. There are also limited labs available to perform the testing. The expense for confirmatory testing is not known at this time.
An alternate strategy is testing with another manufacturer’s licensed EIA test. Testing for anti-HTLV provides a precedence for this strategy since there is no licensed confirmatory testing. The California State Department of Health allows dual EIA tests before suggesting further evaluation.

The limitations to this strategy include waiting for the licensing of an alternative EIA test for Chagas disease. This also emphasizes the importance of saving repeat reactive samples and those that are confirmed positive.

We will need FDA guidance regarding donor deferral and/or re-entry policies; however, this strategy could be used immediately for counseling purposes.
The predicted national prevalence rate of one in 25,000 would yield approximately 400 confirmed positive tests per 10 million donors tested. These positive test results would not be uniformly distributed geographically since we know that the percentage of Hispanic origin donors is not distributed uniformly.

We would expect that components from all prior donations from confirmed positives would be recalled and recipient tracing and lookback required. Testing prior recipients could be expensive.

Component retrieval from prior donations from current repeat reactive donations would also be expected per the AABB recommendations.
Currently, one manufacturer, Ortho-Clinical Diagnostics, has received FDA approval for a Chagas disease test kit. This testing is performed on the Ortho Summit analyzer. Abbott is currently developing a test using recombinant T. cruzi antigens for use on the Prism.

The American Red Cross and Blood Systems, Inc. implemented universal screening in January 2007. It will be interesting to see how the strategies for testing for Chagas disease evolve in the future.

I will be presenting the quiz questions regarding Chagas disease and testing following a question & answer period. Do we need to say this?
Chagas Disease Quiz

Multiple Choice

5. Ortho received license for T. cruzi antibody test in December, 2006. Both ARC and Blood Systems implemented universal testing in (which month?), 2007?
   a. January
   b. February
   c. March
   d. None of the above only selective testing is being done

Please click your mouse or press the page down key to display the correct answer. And the final answer is January. This test is not required by the FDA; however, as indicated two of the largest blood collection organizations have elected to implement testing for Chagas disease.
After participating in the presentation, we expect you to be able to:

- discuss the epidemiology of Chagas disease
- explain the risk of transfusion-transmitted Chagas disease in the US blood supply
- discuss the differences in screening strategies and
- understand the argument for implementing screening for T. cruzi.

Implementation of testing for Chagas disease in one additional way to keep our blood supply as safe as possible.
Introduction

This glossary has been provided as an additional resource for your use. When using the glossary you may click on a term listed in the panel to the left, or select from the alphabet displayed at the top of the screen, or use the search function.

At any time during or after this presentation you may access the glossary.
To receive P.A.C.E CEU Credits

Complete both the Post-Test (Post-Test) and Evaluation (Evaluation)

Once you have completed the Post-Test and Evaluation, submit them by clicking the Submit Post-Test and Evaluation link.

Your Post-Test will be scored automatically upon submission.

If you passed the test, you will be able to download your personalized P.A.C.E. Certificate.
I would like to say thank you for your time and for participating in the SCABBinar. Once this presentation is finished please complete the worksheet and hand it into your instructor.

Thank you.