

First Year Experience of Trypanosoma cruzi Blood Donor Screening



Background

T. Cruzi is a flagellated, protozoan parasite, endemic to Latin American regions and the causative agent of Chagas' disease. FDA licensed the first blood donor screening assay for antibodies to Trypanosoma cruzi (T. cruzi) in December 2006 and our laboratory implemented the assay in January 2007. We report results from a 12-month study that evaluated assay performance and demographic data of positive donations in a blood donor population.

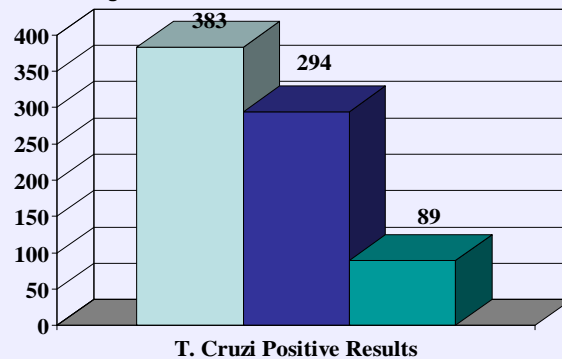
Methods

Routine donor screening was performed using the Ortho-Clinical Diagnostics enzyme-linked immunosorbent assay for the qualitative detection of antibodies to Trypanosoma cruzi (T. cruzi). See Figures 1-2. Specimens with absorbance values greater than or equal to the cutoff value were considered initially reactive (IR) and retested in duplicate. After retesting an IR sample, it was considered repeatedly reactive (RR) for antibodies if either or both duplicate tests were reactive. Results were used to determine the assay's performance to detect T. Cruzi antibodies in the blood donor population and the incidence of confirmed positive donors. Confirmatory testing was performed using the Radioimmune Precipitation Assay (RIPA). The overall specificity rate for the assay was calculated: (# Negative + # Confirmed Positive)/Total Tested.

Results (Figure 3):

Between January and December 2007, there were 2,258,140 samples tested with 99.98% (2,257,757) negative and 0.02% (383) initially reactive (IR) donations. Within the IRs, 77% (294) were repeatedly reactive (RR) and 23% (89) false positive. The overall RR rate was 0.013%. Specificity calculated at greater than 99.99%.

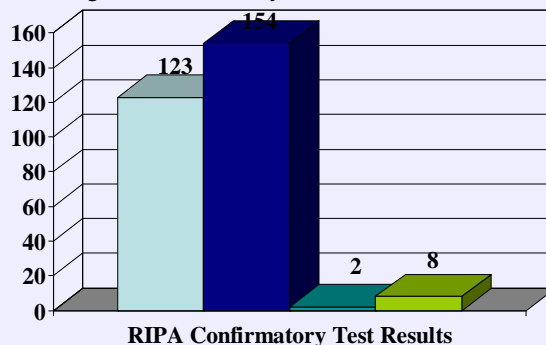
Figure 3: T. cruzi Positive Results



Legend: Initial Reactive (light blue), Repeat Reactive (dark blue), Repeat NonReactive (teal)

A total of 287 of the 294 RR samples were evaluated by RIPA confirmatory (97.6%): results were 53.7% (154) negative, 42.9% (123) RIPA positive, 0.7% (2) indeterminate and 2.8% (8) were unacceptable for testing. (Figure 4)

Figure 4: Confirmatory Results

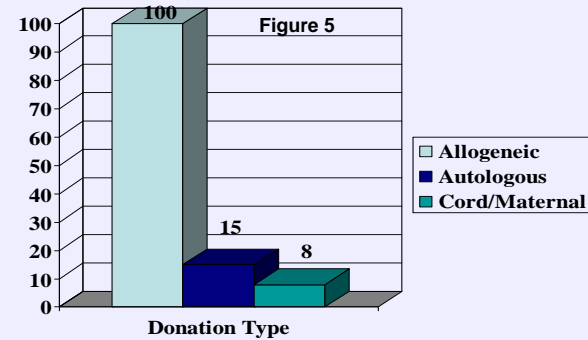


Legend: Positive (light blue), Negative (dark blue), Indeterminate (teal), Sample Unacceptable (yellow-green)

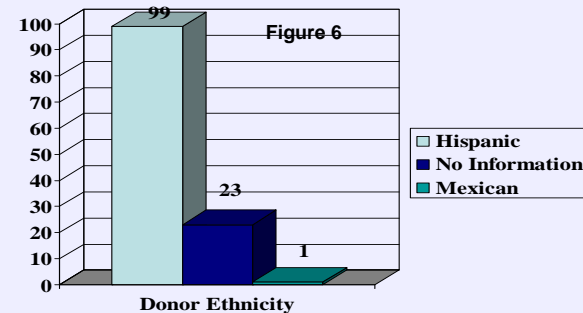
Within the 123 RIPA positive donors:

Location: the highest number, 51.2% (63) were found in California, the second highest number in New York, 14.6% (18), and 34% (42) in many locations. Birth Countries included: 56.1% (69) unknown, 14.6% (18) Mexico, 12.2% (15) USA, 8.13% (10) El Salvador, 3.3% (4) Bolivia and 5.7% (7) from Central America, South America and China.

Donation type (Figure 5): 81.3% (100) were allogeneic, 12.2% (15) were autologous and 6.5% (8) were cord or maternal blood samples.



Ethnicity data (Figure 6): indicated that 80.5% (99) were Hispanic, 18.7% (23) had other or no information and 0.8% (1) was Mexican.



Conclusion

This single site report showed excellent specificity of the T. cruzi antibody assay in a large volume blood donor screening laboratory. The majority of the confirmed positive donations were from Hispanic 80.5%, and allogeneic donors, 81.3%. The highest geographical prevalence of T. cruzi positive donors within the population evaluated was in California.

Figure 1



Figure 2



Session I

TTID2: Parasites

Abstract: SP232

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