TechnicalCommunication

Additional Information for the FMH RapidScreen

This communication provides additional information for interpreting FMH RapidScreen results.

Fetal Bleed Screening Test (Old Test Method)	**Positive Test**[1]
	After examining nine low-power fields, if there are 3 or more clumps of agglutinated red blood cells are observed (i.e. on average, equal to or greater than one clump per three low-powered fields), the test is positive and indicates the presence of D-positive fetal red blood cells in possibly significant numbers in the maternal blood
	Negative Test[1]
	After examining nine low-power fields, if two or fewer clumps of agglutinated red blood cells are observed (i.e. on average, less than one clump per three low-power fields), the test is negative, indicating that a large feto-maternal hemorrhage did not occur.
	Specific Performance Characteristics[1]
	Fetal Bleed Screening Test, if carried out strictly in accordance with the recommended test procedure, will detect feto-maternal hemorrhage whenever 30 mL or more of ABO-compatible D-positive fetal blood has entered the maternal circulation. Depending on the care taken in carrying out the test, a positive result may be obtained when the extent of feto-maternal bleeding is less than 30 mL, but the test is designed to give a negative result when, as in most cases, the amount of fetal bleeding is small (e.g., less than 2 mL of whole blood).

[1] *Fetal Bleed Screening Test – Insert Code: 384-5, Revised 10/10*

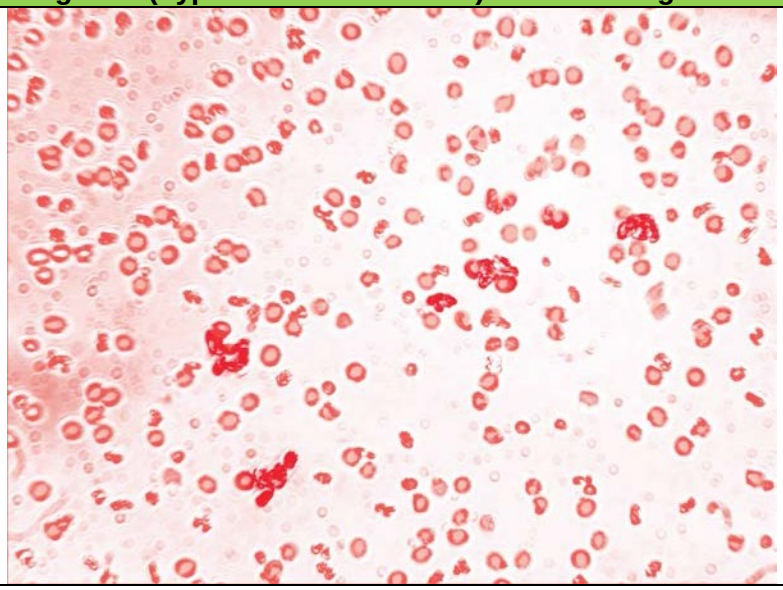
FMH Rapid Screen (New Test Method)	**Positive Test**[2]
	After examining five low-power fields, if five or more agglutinates of red blood cells are observed, the test is positive and indicates the presence of D-positive fetal red blood cells in possibly significant numbers in the maternal blood.
	Negative Test[2]
	After examining five low-power fields, if four or fewer agglutinates of red blood cells are observed, the test is negative, indicating that a large feto-maternal hemorrhage did not occur.
	Specific Performance Characteristics[2]
	FMH RapidScreen, if carried out strictly in accordance with the recommended test procedure, will detect feto-maternal hemorrhage whenever 30 mL or more of ABO-compatible D-positive fetal blood has entered the maternal circulation. Depending on the care taken in carrying out the test, a positive result may be obtained when the extent of feto-maternal bleeding is less than 30 mL, but the test is designed to give a negative result when, as in most cases, the amount of fetal bleeding is small (e.g. less than 2 mL of whole blood.

[2] *FMH RapidScreen - Insert code: 3047-1, Revised 3/12*

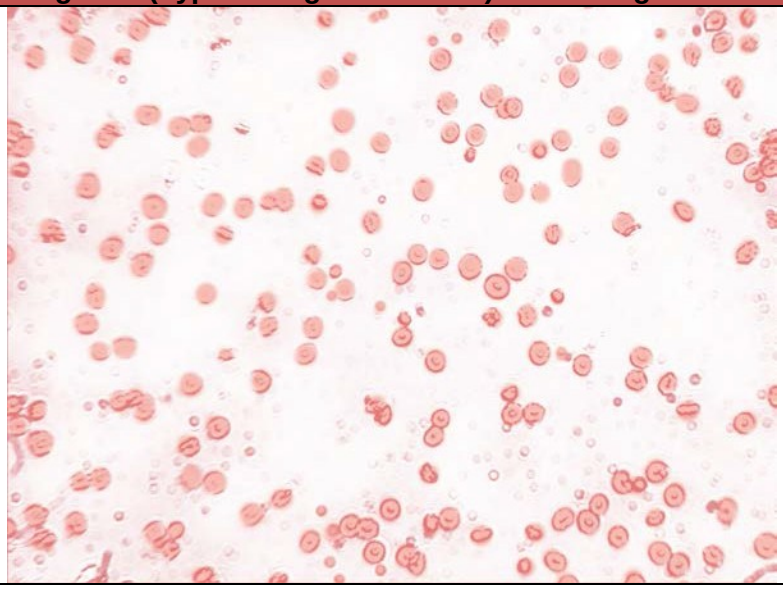
The following are typical examples of positive and negative test results for both the Fetal Bleed Screening Test and the FMH RapidScreen. These images are for reference only and individual results may not appear identical to the images below. Images below are viewed greater than 100x magnification to show detail. Results should be viewed at approximately 100x magnification which typically is performed using a 10x objective lens with a 10x ocular lens.

Fetal Bleed Screening Test

Fetal Bleed Screening Test (Typical Positive Result) at >100x Magnification

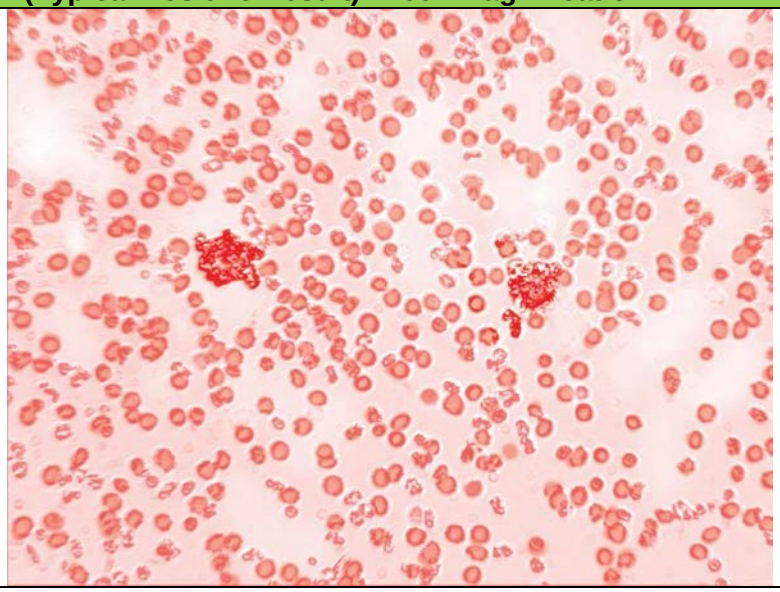


Fetal Bleed Screening Test (Typical Negative Result) >100x Magnification

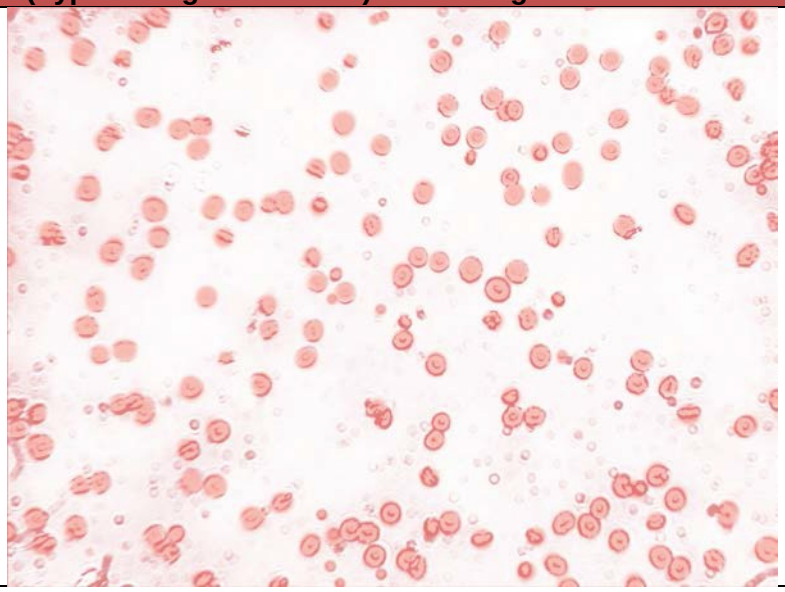


FMH RapidScreen

FMH RapidScreen (Typical Positive Result) >100x Magnification



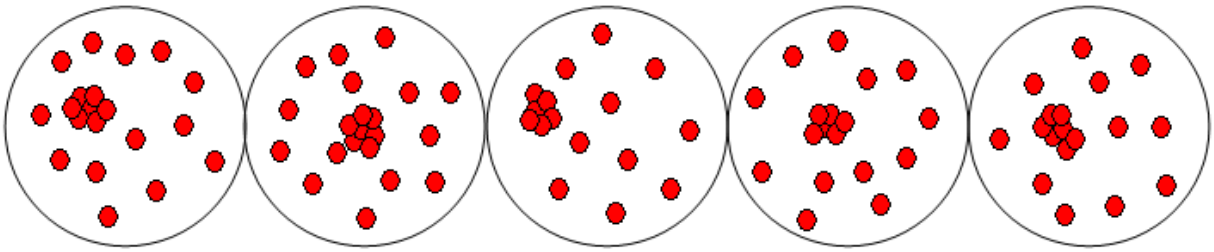
FMH RapidScreen (Typical Negative Result) >100x Magnification



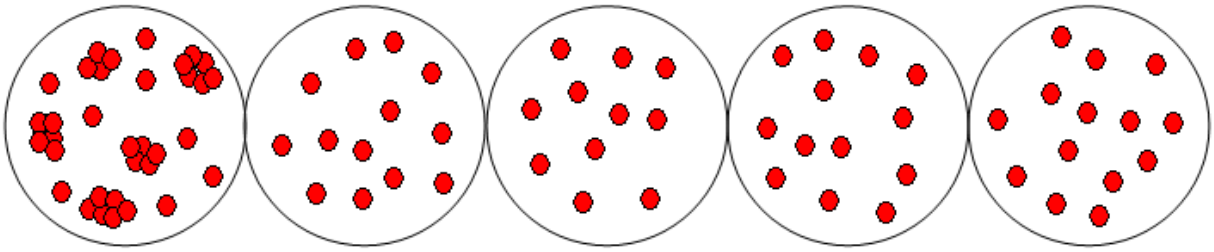
FMH RapidScreen Results Continued

Each Circle represents one 100x low-power field (10x objective lens with 10x ocular lens)

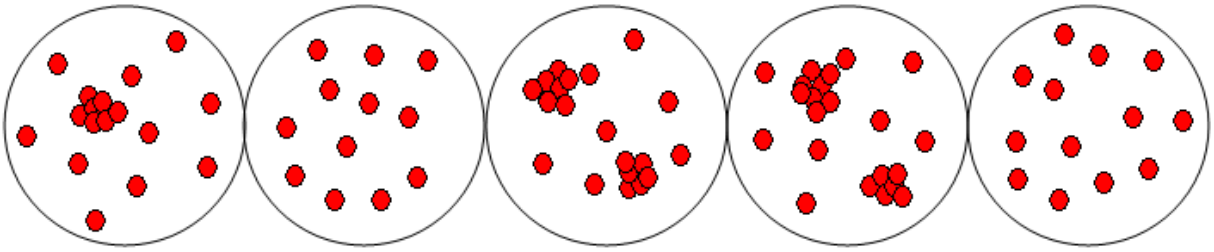
Positive Reaction – Total: 5 Agglutinates



Positive Reaction – Total: 5 Agglutinates



Positive Reaction – Total: 5 Agglutinates



Negative Reaction – Total: 3 Agglutinates