

Epstein-Barr virus

# Epstein Barr Virus

- What is it?
  - **Infectious mononucleosis, Burkitt's lymphoma**
  - **Clinical symptoms mimic other diseases**
    - **sore throat, lethargy, aches**
- **Virus may be reactivated years later**
  - **Important in transplant cases**



# EBV Background/Issues

- **Most common method of testing:**
  - **Heterophile tests (card test)**
    - **Sheep Red blood cells agglutinate**
    - **Typically found with EBV infection**
    - **NOT specific for EBV**

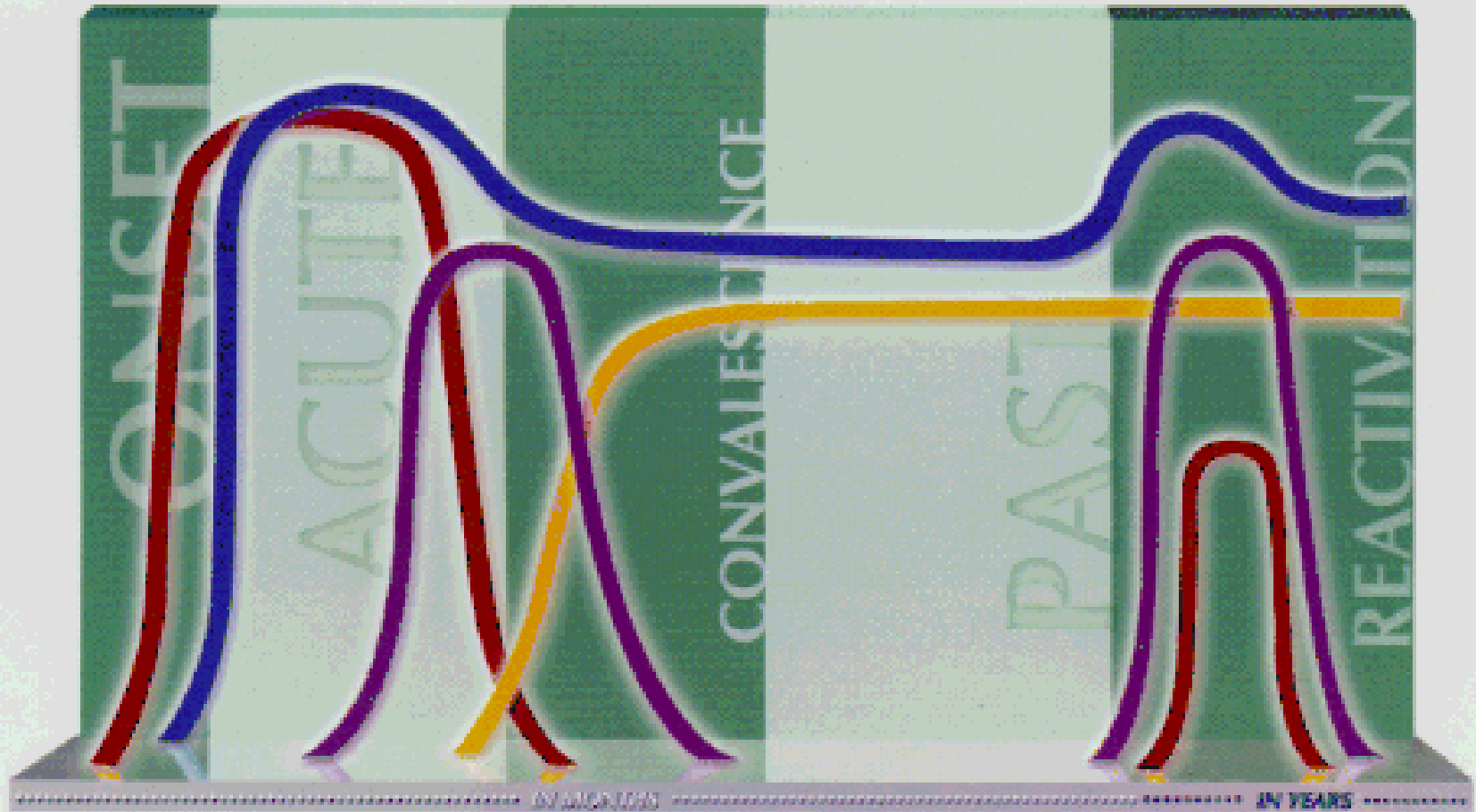
# EBV Background/Issues

- **Heterophile tests (card test)**
  - Manual, subjective
  - 10-20% adults test negative—some pediatric patients may be negative
  - Will be negative in reactivated cases
    - This is a problem for transplant patients!
  - **Measurement of specific Ab PROFILE more clinically significant**

# Diamedix EBV

- 6 kits run as panel to identify stage of disease
  - **EBV VCA IgG** (Viral capsid antigen) **& IgM**
    - VCAs can appear within 1 week of infection
    - IgM precedes IgG
  - **EBNA** (Nuclear antigen) **IgG & IgM**
    - develops 3-4 or many weeks later
  - **EBV Early Antigen (EA) IgG & IgM**
    - Detects EA-D, IgM appears early in infection

# EBV Infection Serological Diagnosis



■ VCA  
■ EBV-M

■ EBNA  
■ EA

# EBV SEROLOGY

	EBV-M	EBV-G			
Disease Condition	VCA IgM	VCA IgG	EBNA	EA	Heterophile
Not exposed	-	-	-	-	-
Primary infection	+	+	-	+/-	adult (85-90% +)
			most = neg.	>80% pos.	children (50% +)
Past infection	-	+	+/-	-/+	-
			majority = pos	20-30% pos.	
Reactivation	-/+	+	+/-	+	-

In the Diamedix tests, VCA IgM appears first, then VCA IgG

# EBV kits

- **VCA IgG 720-600**
  - **VCA IgM 720-610**
  - **EA-D IgG 720-640**
  - **EA-D IgM 720-650**
  - **EBNA-1 IgG – 720-620**
  - **EBNA-1 IgM – 720-630**
- **very pure Ags**
  - **EBV IgG tests share diluent with other kits**
  - **EBV IgM tests have own distinct diluents not shared with any other kit**



# Diamedix EBV

- **Qualitative results**
- **6 cal/control wells/run**
- **Reimbursement \$18-25 each**

# Diamedix EBV VCA IgG Assay

## Comparative Study-Serological Status

EBV Serological Status*	Diamedix Kit			TOTAL
	Positive	Negative	Equivocal	
Past	99	0	3	102 (a)
Current	28	5	6	39 (b)
Seronegative	2	30	2	34 (c)
TOTAL	129	35	11	175

Equivocal specimens were excluded from calculations

### \* SAMPLE CATEGORIES:

(a) Past= VCA-G and/or EBNA G POS, VCA M and heterophile AB NEG

(b) Current= VCA M and/or heterophile POS, EBNA G NEG

(c) Seronegative= VCA G, VCA M, EBNA G and heterophile NEG

### RELATIVE STATISTICS

Overall Agreement compared to serological status was  $157/164 = 95.7\%$

Diamedix 510(k) submission data

# EBV Competition

- **Heterophile tests**
  - **Mono Spot**
  - **Paul Bunnell**
  - **will be negative if virus is reactivated.**
    - **Problem for transplant cases!!**
    - **If using this method, how can you be sure you will detect EBV?**
- **IFA**
- **Other EIA**