



# **Increasing Detection of Malaria in U.S. Hospitals**

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# Goals

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- **Increase detection of malaria in the United States**
  - **Introduce new technology for rapid malaria diagnosis**
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# Objectives

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- Evaluate a rapid malaria diagnostic test in US hospitals
  - Determine the level of acceptance of new rapid test technology
  - Determine sensitivity/specificity
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# Rationale

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- U.S. hospital laboratory personnel see very few malaria cases – may miss malaria on blood films
  - Test provides tool to diagnose patients who come into ER on nights/weekends when laboratory closed.
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# Reported Malaria in US

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<u>Year</u>	<u>Malaria Cases</u>
1993	1,275
1994	1,014
1995	1,167
1996	1,392
1997	1,544
1998	1,227

Holtz et al., MMWR, 2001 50:1-18

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# Species Distribution -US

	<u>1997</u>	<u>1998</u>
<b>falciparum</b>	<b>567</b>	<b>525</b>
<b>vivax</b>	<b>755</b>	<b>464</b>
<b>malariae</b>	<b>48</b>	<b>43</b>
<b>ovale</b>	<b>31</b>	<b>26</b>
<b>undet.</b>	<b>134</b>	<b>162</b>
<b>mixed</b>	<b>9</b>	<b>7</b>
<b>TOTAL</b>	<b>1544</b>	<b>1227</b>

Source: Holtz et al., MMWR, 2001 50(1-18)

# OptiMAL Rapid Malaria Test (Flow Inc., Portland, OR)

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- Detects pLDH
  - Differentiates *falciparum* from non-*falciparum*
  - Can follow drug therapy
  - Completed on only a finger stick of blood
  - Results in 15 minutes
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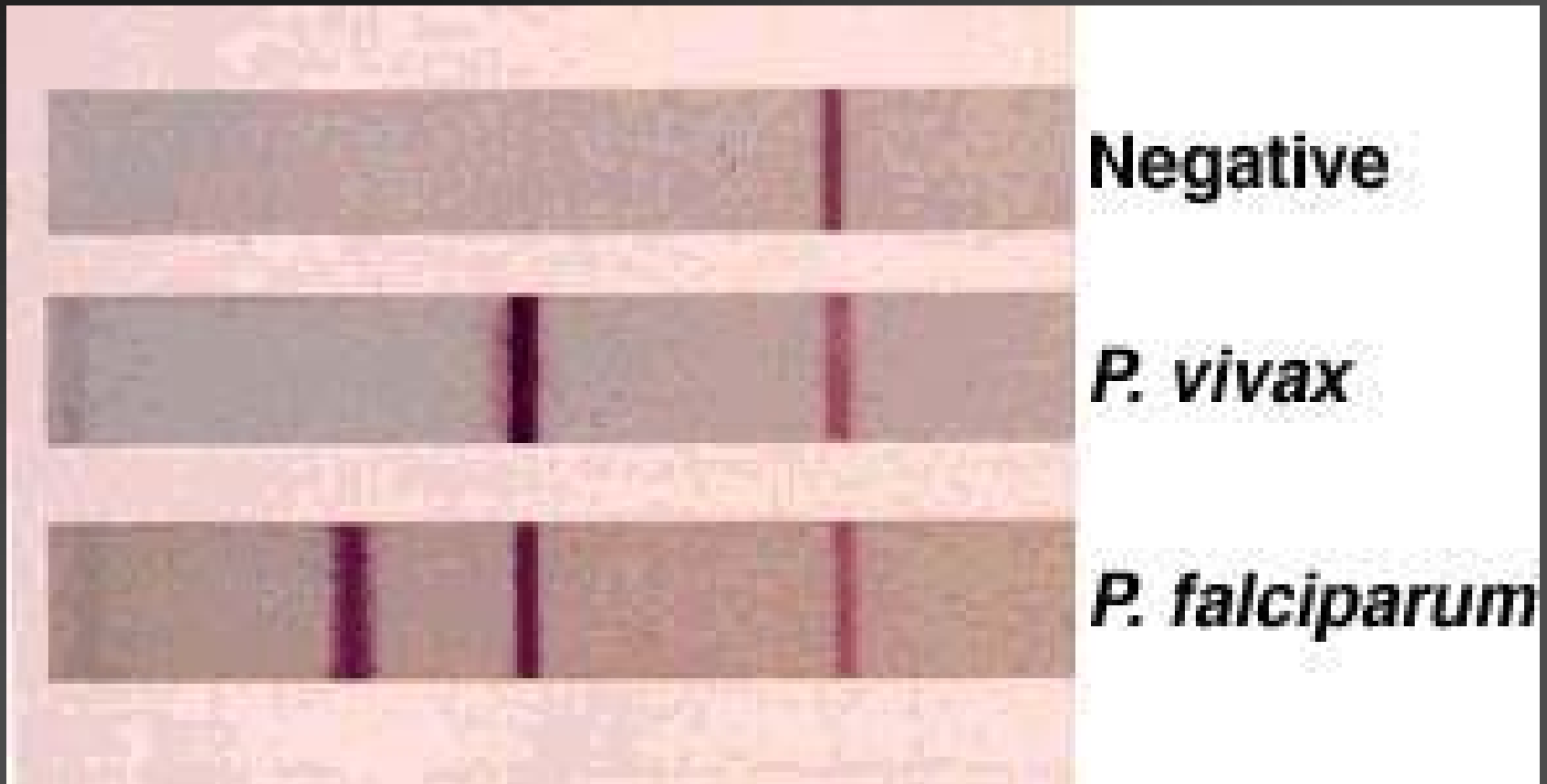
# OptiMAL Rapid Malaria Diagnostic Test (Flow Inc.)

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- Dispense 30  $\mu$ l of Buffer into well. Add 10  $\mu$ l blood/mix well
  - Add OptiMAL<sup>®</sup> test strip/allow sample to wick up the test strip
  - Move the test strip to a second wash well containing Buffer
  - Read the test strip after the blood color has cleared - 15 min
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# OptiMAL Result Outcomes



# Study Design

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- Hospitals had to see >10 cases of malaria /yr
  - Each hospital obtained individual IRB approval
  - 100 OptiMAL test strips were given to each site
  - Suspect malaria patients diagnosed with blood films
  - OptiMAL rapid test completed on left-over blood
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# Results to Date

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- 83 patients tested
  - 19 positive bloodfilm (13 falciparum, 6 vivax)
  - 18 positive by OptiMAL (13 falciparum, 5 vivax).
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# Discrepant Result

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- 1 Bloodfilm positive/OptiMAL negative
  - Further testing revealed the sample as *Babesia* positive/malaria negative
  - OptiMAL correctly identified the case as malaria negative
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# Sensitivity/Specificity

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## ■ Sensitivity

- 12 positive by both microscopy and OptiMAL
- 100% sensitivity

## ■ Specificity

- 71 negative by bloodfilm
  - 100% specificity
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# Origin of Malaria Cases in Study to Date

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- Nigeria, Kenya, Uganda,
  - Senegal, Gambia, Ghana,
  - Sudan, Iraq, India,
  - Ecuador, Indonesia, Bangladesh
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# Cost of Hospital Diagnosis of Malaria

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- Ranges from \$75-\$100 for bloodfilm microscopy
  - OptiMAL - currently marketed for \$3.00 per test
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# Discussion

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- **OptiMAL is perceived as asset in diagnostic labs - esp in ER (nights/weekend applications)**
  - **Hospitals requesting FDA approval for test**
  - **Excellent sens/spec - high parasitemias**
  - **Study concludes August, 2002**
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# Discussion

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- **How many samples tested per year?  
Actual number could be much higher  
than cases**
  - **Test should increase detection of  
malaria in the US**
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# Recommendations

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- **FDA approval needed for rapid malaria diagnostic test**
    - **Test currently used globally except US**
  - **Test could be improved to differentiate all four human malaria species**
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