

Detects	<i>Plasmodium</i> sp. (<i>Plasmodium falciparum</i> , <i>Plasmodium vivax</i> , <i>Plasmodium ovale</i> , <i>Plasmodium malariae</i> , and <i>Plasmodium knowlesi</i>)																																																																																																		
Target	The <i>illumigene</i> [®] Malaria assays target a 214 base pair (bp) sequence of a <i>Plasmodium</i> sp. mitochondrial DNA noncoding region.																																																																																																		
Acceptable Sample Types	Human venous EDTA whole blood specimens																																																																																																		
Turnaround Time	Less than 1 hour																																																																																																		
Storage Requirements	Kits should be stored at 2-30 C.																																																																																																		
Shelf Life	12 months																																																																																																		
Sample Storage	EDTA venous whole blood samples may be stored at 2-30 C after collection and during transportation to the laboratory. Samples should be tested as soon as possible, but may be stored for up to 7 days at room temperature (19-30 C) or up to 14 days refrigerated (2-8 C) prior to testing. Samples that will not be tested within this time frame should be frozen immediately at -20 C for up to 30 days until tested. Samples may be frozen and thawed 2 times after storage at -20 C prior to testing with the <i>illumigene</i> [®] Malaria assays.																																																																																																		
Clinical Performance	<p>The performance characteristics of the <i>illumigene</i>[®] Malaria and <i>illumigene</i>[®] Malaria PLUS DNA Amplification Assays were established in clinical studies conducted in Senegal, Africa. Performance characteristics of the assay were compared to the reference method, thin and thick film microscopy. <i>Plasmodium</i> species identification for all positive samples was determined by microscopy.</p> <p><i>illumigene</i>[®] Malaria Performance Compared to Microscopy</p> <table border="1"> <thead> <tr> <th colspan="2" rowspan="2"></th> <th colspan="3">Microscopy</th> <th><i>illumigene</i>[®]</th> <th colspan="4">Performance</th> </tr> <tr> <th>Pos</th> <th>Neg</th> <th>Total</th> <th>INV</th> <th colspan="2"></th> <th>95% CI</th> </tr> </thead> <tbody> <tr> <td rowspan="3"><i>illumigene</i>[®] Malaria</td> <td>Pos</td> <td>139</td> <td>8</td> <td>147</td> <td>0(1)</td> <td>Sensitivity</td> <td>100.0%</td> <td>139/139</td> <td>97.3-100.0%</td> </tr> <tr> <td>Neg</td> <td>0</td> <td>67</td> <td>67</td> <td>2(2)</td> <td>Specificity</td> <td>89.3%</td> <td>67/75</td> <td>80.3-94.5%</td> </tr> <tr> <td>Total</td> <td>139</td> <td>75</td> <td>214</td> <td>2</td> <td colspan="4"></td> </tr> </tbody> </table> <p><i>illumigene</i>[®] Malaria PLUS Performance Compared to Microscopy</p> <table border="1"> <thead> <tr> <th colspan="2" rowspan="2"></th> <th colspan="3">Microscopy</th> <th><i>illumigene</i>[®]</th> <th colspan="4">Performance</th> </tr> <tr> <th>Pos</th> <th>Neg</th> <th>Total</th> <th>INV</th> <th colspan="2"></th> <th>95% CI</th> </tr> </thead> <tbody> <tr> <td rowspan="3"><i>illumigene</i>[®] Malaria PLUS</td> <td>Pos</td> <td>136</td> <td>13</td> <td>149</td> <td>0</td> <td>Sensitivity</td> <td>100.0%</td> <td>136/136</td> <td>97.3-100.0%</td> </tr> <tr> <td>Neg</td> <td>0</td> <td>62</td> <td>62</td> <td>0</td> <td>Specificity</td> <td>82.7%</td> <td>62/75</td> <td>72.6-89.6%</td> </tr> <tr> <td>Total</td> <td>136</td> <td>75</td> <td>211</td> <td>0</td> <td colspan="4"></td> </tr> </tbody> </table> <p><i>*Initial invalid results are reported within the parentheses. The final number of invalid samples remaining after repeat testing is shown before the parenthesis.</i></p>											Microscopy			<i>illumigene</i> [®]	Performance				Pos	Neg	Total	INV			95% CI	<i>illumigene</i> [®] Malaria	Pos	139	8	147	0(1)	Sensitivity	100.0%	139/139	97.3-100.0%	Neg	0	67	67	2(2)	Specificity	89.3%	67/75	80.3-94.5%	Total	139	75	214	2							Microscopy			<i>illumigene</i> [®]	Performance				Pos	Neg	Total	INV			95% CI	<i>illumigene</i> [®] Malaria PLUS	Pos	136	13	149	0	Sensitivity	100.0%	136/136	97.3-100.0%	Neg	0	62	62	0	Specificity	82.7%	62/75	72.6-89.6%	Total	136	75	211	0				
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Analytical Sensitivity	<p>Limit of Detection (LoD) was determined using <i>Plasmodium falciparum</i> and <i>Plasmodium vivax</i>. The LoD was confirmed using 20 replicates and a stated probability (eg, 95%, where 19/20 replicates are positive) of obtaining positive responses.</p> <table border="1"> <thead> <tr> <th rowspan="2"><i>Plasmodium</i> Species</th> <th><i>illumigene</i>[®] Malaria</th> <th><i>illumigene</i>[®] Malaria PLUS</th> </tr> <tr> <th>Parasites/μL</th> <th>Parasites/μL</th> </tr> </thead> <tbody> <tr> <td><i>P. falciparum</i> (3D7)</td> <td>2</td> <td>0.25</td> </tr> <tr> <td><i>P. vivax</i> (India VII)</td> <td>0.125</td> <td>0.063</td> </tr> </tbody> </table>									<i>Plasmodium</i> Species	<i>illumigene</i> [®] Malaria	<i>illumigene</i> [®] Malaria PLUS	Parasites/μL	Parasites/μL	<i>P. falciparum</i> (3D7)	2	0.25	<i>P. vivax</i> (India VII)	0.125	0.063																																																																															
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Assay Reactivity	Quantified stocks of <i>P. malariae</i> , <i>P. ovale</i> , and <i>P. knowlesi</i> DNA were diluted in negative whole blood to approximately three times the limit of detect for each <i>illumigene</i> [®] Malaria and <i>illumigene</i> [®] Malaria PLUS sample preparation method (approximately 72 copies/μL or 6 parasites/μL for <i>illumigene</i> [®] Malaria; approximately 9 copies/μL or 0.75 parasites/μL for <i>illumigene</i> [®] Malaria PLUS). All species reacted at the concentrations tested.																																																																																																		
Ordering Info	<ul style="list-style-type: none"> <i>illumigene</i>[®] Malaria (25 tests/kit) 280925 <i>illumigene</i>[®] Malaria PLUS (25 tests/kit) 281125 <i>illumigene</i>[®] Malaria External Control Kit (18 uses each) 279970 																																																																																																		



Please refer to the most current version of the Package Insert for complete instructions.

For more information, contact a specialist at info@meridianbioscience.eu.

REFERENCE

1. *illumigene*[®] Malaria Package Insert, SN11102

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