

## Product Gap Analysis – Interpretation Guide

Diagnostic tools	2	1	0	-1	-2	Coefficient 4.17	Score /100
<b>1. Availability</b>	Not available None available in spite of research	Low Only in highly specialised laboratories	Moderate Kits developed by laboratories	High Commercial kits available at lab level	Very high Commercial kits available at vet/farm level		
<b>2. Prevention and control Differentiation of infected from vaccinated (DIVA)</b>	No tests available	DIVA Tests In development	DIVA Tests available but not tested under field conditions	Commercially available DIVA tests in Europe but only partially effective	Commercially available approved tests in Europe and fully effective		
<b>3. Strategic reserve</b>	None	Very low Poor level of reserves for any emergency with poor storage characteristics	Low Adequate level of reserves for any emergency with good storage characteristics for short periods	Medium Good level of reserves for any emergency with good storage characteristics for intermediate periods	Fully acceptable Very good level of reserves for any emergency with good storage characteristics for long periods		
<b>4. Capacity of production</b>	Very restricted.	Restricted and requires notification of demand well in advance	Limited but requires early notification of demand	Limited but meets specific demands	Unlimited meet any market demands		
<b>5. Affordable</b>	Too expensive to be used	Expensive but affordable for developed countries only in some circumstances but not	Affordable for developed countries but expensive for developing countries	Fully affordable for developed countries But expensive for developing countries	Fully affordable for developing and developed countries		

		for developing countries					
6. Quality/stability durability	Very poor stability < 3months with temperature control needed.	Poor stability 3-6 months under temperature controlled environment	Acceptable stability 6-12 months, no temperature requirements	Good stability 24 month shelf life, no temperature requirements	High stability Indefinite shelf life No temperature requirements		
7. Sensitivity	Very low Less than 60 %	low 60 to 70 %	medium 70 to 80%	high 80 to 99%	Very high 100%		
8. Specificity	Very low Less than 60 %	low 60 to 70 %	medium 70 to 80%	high 80 to 99%	Very high 100%		
9. Reproducibility	Very low Less than 60 %	low 60 to 70 %	medium 70 to 80%	high 80 to 99%	Very high 100%		
10. Simplicity/ease of use	Extremely difficult Specific courses and training required at main lab	Moderately difficult Training required off site	Difficult Training required	Easy to use, Training required	Very easy to use Minimal training required		
11. Speed	Very slow Results > 4 days	Slow Results within 4 days	Quick Results within 24 hours	Rapid Results with 4 hours	Very rapid Results within 1 hour		

Vaccination tools	2	1	0	-1	-2	Coefficient 4.55	Score /100
1. Commercial availability	Not available	In development	Available elsewhere outside EU, Us, Australia	Available in the US or Australia	Fully available and authorised in Europe		
2. Monitoring for infection in a vaccinated population	Tool(s) not available	Tool(s) In development	Tool(s) available but not tested under field conditions	Commercially available authorised tool(s)in Europe but only partially effective	Commercially available authorised tool(s) in Europe and fully effective		

<b>3. Strategic reserve</b>	<b>None</b>	<b>Very low</b> Poor level of reserves for any emergency with poor storage characteristics	<b>Low</b> Adequate level of reserves for any emergency with good storage characteristics for short periods	<b>Medium</b> Good level of reserves for any emergency with good storage characteristics for intermediate periods	<b>Fully acceptable</b> Very good level of reserves for any emergency with good storage characteristics for long periods		
<b>4. Capacity of production</b>	<b>Very restricted.</b>	<b>Restricted and requires notification of demand well in advance</b>	<b>Limited but requires early notification of demand</b>	<b>Limited but meets specific demands</b>	<b>Unlimited meet any market demands</b>		
<b>5 Affordable</b>	<b>Too expensive to be used</b>	<b>Expensive but affordable for developed countries only in some circumstances but not for developing countries</b>	<b>Affordable for developed countries but expensive for developing countries</b>	<b>Fully affordable for developed countries But expensive for developing countries</b>	<b>Fully affordable for developing and developed countries</b>		
<b>6. Quality/stability</b>	<b>Very poor stability</b> Cold chain required at all times	<b>Poor stability</b> Cold chain required but 30 mins leeway prior to application	<b>Acceptable stability</b> Cold chain required but 2 hours leeway prior to application	<b>Good stability</b> Cold chain required but 12 hours leeway prior to application	<b>High stability</b> Thermostable with no cold chain required.		
<b>7. Safety of vaccines</b>	<b>Severe local and systemic reactions including morbidity, mortality in combination with shedding</b>	<b>Moderate local and systemic reactions including morbidity, in combination with shedding</b>	<b>Moderate local and systemic reactions in combination with shedding</b>	<b>Local reactions, no systemic and no shedding</b>	<b>No local or systemic reaction and no shedding</b>		
<b>8. Efficacy</b>	<b>Not efficacious against any strains</b>	<b>Partially efficacious against a single strain</b>	<b>Fully efficacious against single strain</b>	<b>Partially efficacious vaccine against all strains</b>	<b>Fully efficacious vaccine against all strains</b>		

9. Immunity	< 6months immunity following two doses	6mths – 1 yr immunity following two doses	> 1yr immunity following single dose	Lifelong immunity following two doses	Lifelong immunity following single dose		
10. Convenience of use	multiple individual handling	individual handling	automatic individual vaccination	multiple herd application	single herd application		

Pharmaceutical tools	2	1	0	-1	-2	Coefficient 4.55	Score /100
1. Availability	None No availability at field level	In development	Available elsewhere	Available in the US or Australia or authorised for use in other species within the EU	Fully available and authorised within the EU		
2. Prevention and control	No pharmaceutical tool available for prevention or control	Poorly effective when used for either prevention OR Control	Partially effective when used for either prevention OR Control	Fully effective when used for either prevention OR Control	Fully effective when used for both prevention and control		
3. Strategic reserve	none	Very low Poor level of reserves for any emergency with poor storage characteristics	Low Adequate level of reserves for any emergency with good storage characteristics for short periods	Medium good level of reserves for any emergency with good storage characteristics for intermediate periods	Very good Fully acceptable Very good level of reserves for any emergency		
4. Capacity of production	none	negligible	low	Medium	high		

5. Cost	Too expensive to be used	Expensive but affordable for developed countries only in some circumstances but not for developing countries	Affordable for developed countries but expensive for developing countries	Fully affordable for developed countries But expensive for developing countries	Fully affordable for developing and developed countries		
6. Quality	Non existent	poor	low	medium	high		
7. Safety – animal	Toxic compound not susceptible to risk management measures	Residual risk acceptable using risk management measures	Safety concerns fully controlled through risk management measures	Minor safety concerns that are readily managed without need for specific measures	No safety concerns		
8. Safety – Consumer/user concerns	Toxic compound not susceptible to risk management measures	Residual risk acceptable using risk management measures	Safety concerns fully controlled through risk management measures	Minor safety concerns that are readily managed without need for specific measures	No safety concerns		
9. Safety - Environment	Toxic compound not susceptible to risk management measures	Residual risk acceptable using risk management measures	Safety concerns fully controlled through risk management measures	Minor safety concerns that are readily managed without need for specific measures	No safety concerns		
10. Resistance	Very High Most organisms resistant and easily transferable	High Increasing incidence of resistance with evidence of transferable resistance factors	Moderate Moderate incidence appears stable with some evidence of transference of resistance	low Low incidence, not changing and little evidence of transference of resistance	None None known And not known to develop		