



# Expert panels on medical devices and *in vitro* diagnostic medical devices (Expamed)

*Ongoing performance evaluation under the IVD*

## Administrative information

---

<b>Internal PECP dossier #</b>	IVD-2024-000020
--------------------------------	-----------------

## Ongoing performance evaluation consultation procedure

<b>Tick to confirm</b> <input checked="" type="checkbox"/>	There are currently no relevant CS available for the class D device under assessment
---	--

<b>Intended purpose (P)</b>		
P1	what is detected and/or measured <i>please specify the analyte(s) or marker(s), e.g. SARS-CoV-2 spike protein, Kel1 (K)</i>	Fetal RHD status (exons 5, 7 and 10 of the RHD gene)
P2	function of the device <i>e.g. diagnosis, aid to diagnosis, monitoring, determining the infectious load, tissue typing etc</i>	Aid to decide if a prepartum anti-D prophylaxis should be administered to RhD-negative pregnant women
P3	the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate <i>e.g. hepatitis C infection, exposure to SARS-CoV-2, risk of HIV transmission in blood transfusion etc.</i>	RHD status of the fetus, as a RhD-positive fetus causes the formation of anti-D IgG antibodies in an RhD-negative mother
P4	whether it is automated or not	Non-automated assay
P5	whether it is qualitative, semi-quantitative or quantitative	Qualitative assay
P6	type of specimen(s) <i>e.g. whole blood, serum, saliva etc</i>	Extracted human maternal plasma
P7	where applicable, the testing population <i>e.g. persons with specific health conditions, persons with specific symptoms, children in a certain age range</i>	Non-immunized RhD-negative pregnant women
P8	intended user	For Professional Use Only (trained users)
<b>Technology (T)</b>		
T1	principle of the assay method or principles of operation of the instrument <i>e.g. real-time PCR, qualitative PCR, digital PCR, sandwich immunoassay, competitive immunoassay, immunoturbidimetric assay etc.</i>	Real-time polymerase chain reaction (PCR) – amplification of the specific Target Sequence using fluorescence-labelled oligonucleotide probes