

LUIVAC Symposium

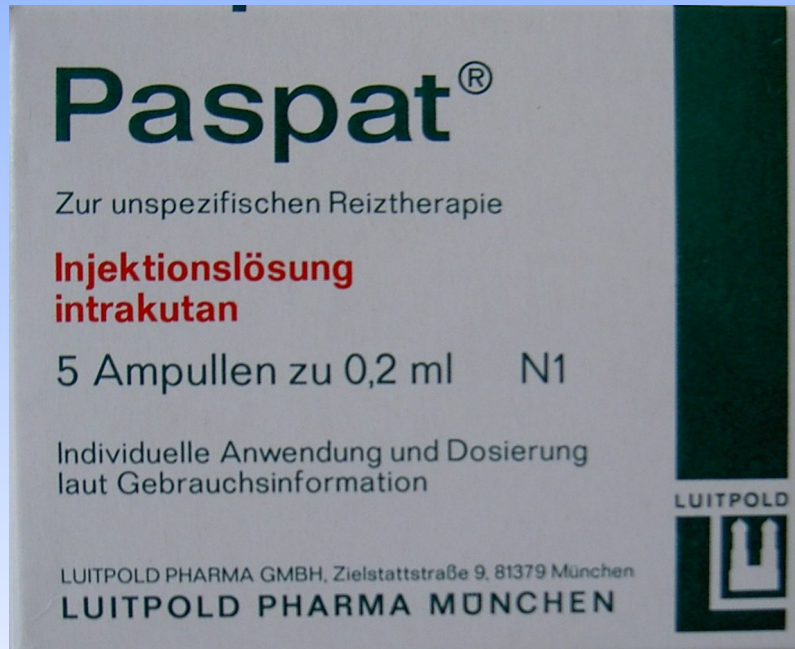
Prague, May 19th, 2006

History of Luivac[®]

Wolfram Raake

Precursor of Luivac[®]

- for specific and unspecific stimulation of the immunsystem



launched in January 1968

Paspat[®] i.c.

1 ampoule of 0.2 ml autolysate contained antigen mixture:

Staphylococcus aureus	30 Mio.
Staphylococcus albus (epidermidis)	30 Mio.
Streptococcus viridans (mitis)	10 Mio.
Streptococcus haemolyticus (pyogenes)	10 Mio.
Diplococcus (Streptococcus) pneumoniae	5 Mio.
Neisseria (Branhamella) catarrhalis	5 Mio.
Haemophilus influenzae	2,5 Mio.
Candida albicans	5 Mio.

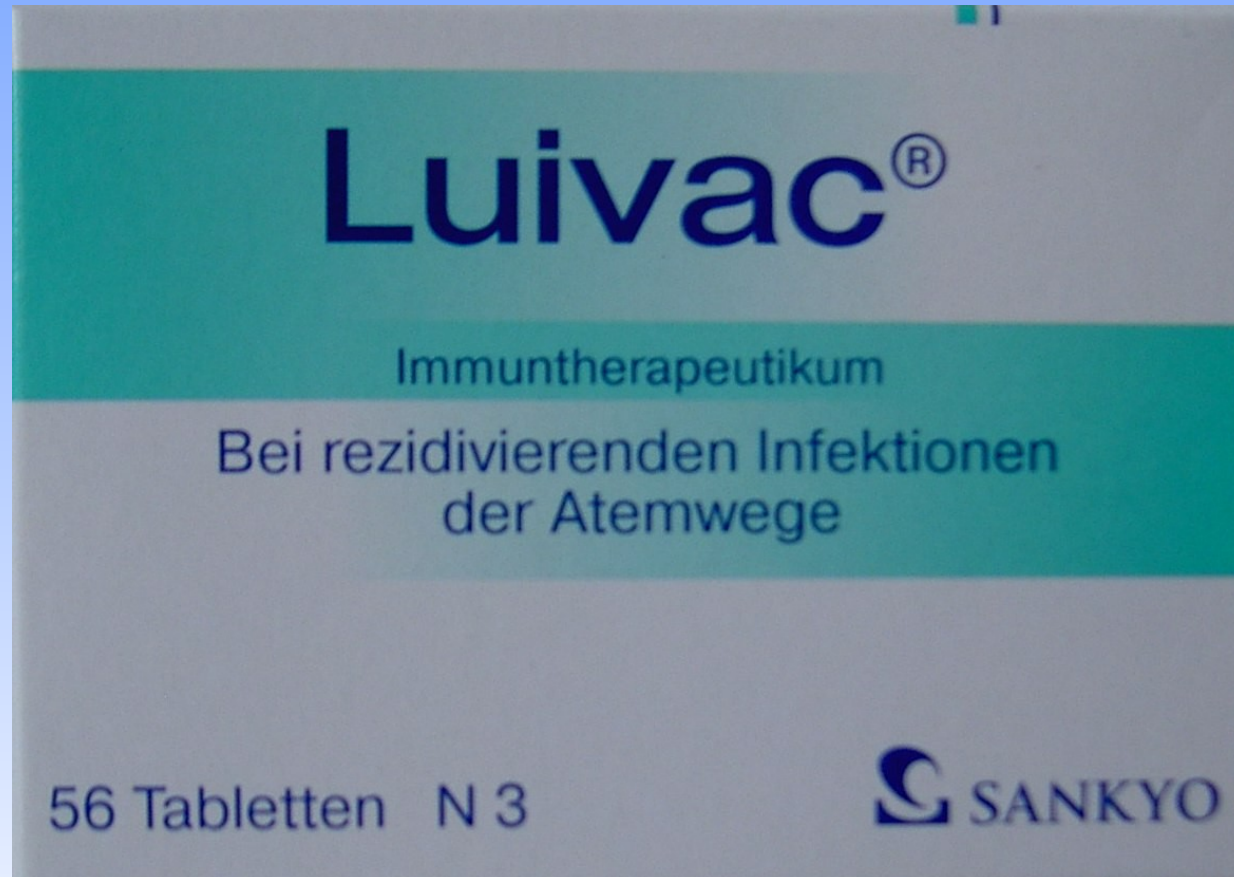
Paspat[®] i.c.

- **injected i.c. 0.2 ml; several wheals**
- **scarified 3x3; or 4x4**
small cores into the skin of the upper part of the thigh
- **repeated treatments necessary:**
 - **in children after 8-12 days**
 - **in adults after 3-5 days**
- **a Paspat cure consists of 10 individual treatments**



Paspat[®] i.c. - Indications

- **asthma bronchiale**
- **allergic rhinitis, otitis and sinusitis**
- **conjunctivitis vernalis**
- **allergic exanthema**
- **increased risk of infections**



Specification of Luivac[®]

Specification of Luivac Raw Material

3 mg of Bacteria lysate mixture of at least 1×10^9 cells of each following strains:

Branhamella catarrhalis	ATCC 8176	0,4 mg
Haemophilus influenzae	ATCC 19418	0,2 mg
Klebsiella pneumoniae	ATCC 13883	0,6 mg
Staphylococcus aureus	ATCC 12600	0,4 mg
Streptococcus mitis	ATCC 6249	0,5 mg
Streptococcus pneumoniae	ATCC 6303	0,3 mg
Streptococcus pyogenes	ATCC 14289	0,6 mg
Active ingredients		3,0 mg

distributed in 40 mg of Mannitol

Luivac[®]

Dosage and method of administration

Immunisation 28 Days	Interval 28 Days	Booster 28 Days
1 tablet per day in the morning on an empty stomach	no treatment	1 tablet per day in the morning on an empty stomach

Luivac[®] - Indications

Luivac is an oral immuno-therapeutic agent for children and adults with recurrent respiratory tract infections

- **bronchitis**
- **rhinitis**
- **sinusitis**
- **otits**
- **pharyngitis**
- **laryngitis**

Production Capacity for Luivac[®]

- **Approx. 80 fermentation batches á 1,2 kg yield**
- **Resulting in 100 kg bacteria lysate p.a.**
- **Sufficient to produce approx. 20 batches Luivac API (active pharmaceutical ingredient) á 70 kg**
- **Resulting in 1400 kg Luivac API p.a.**

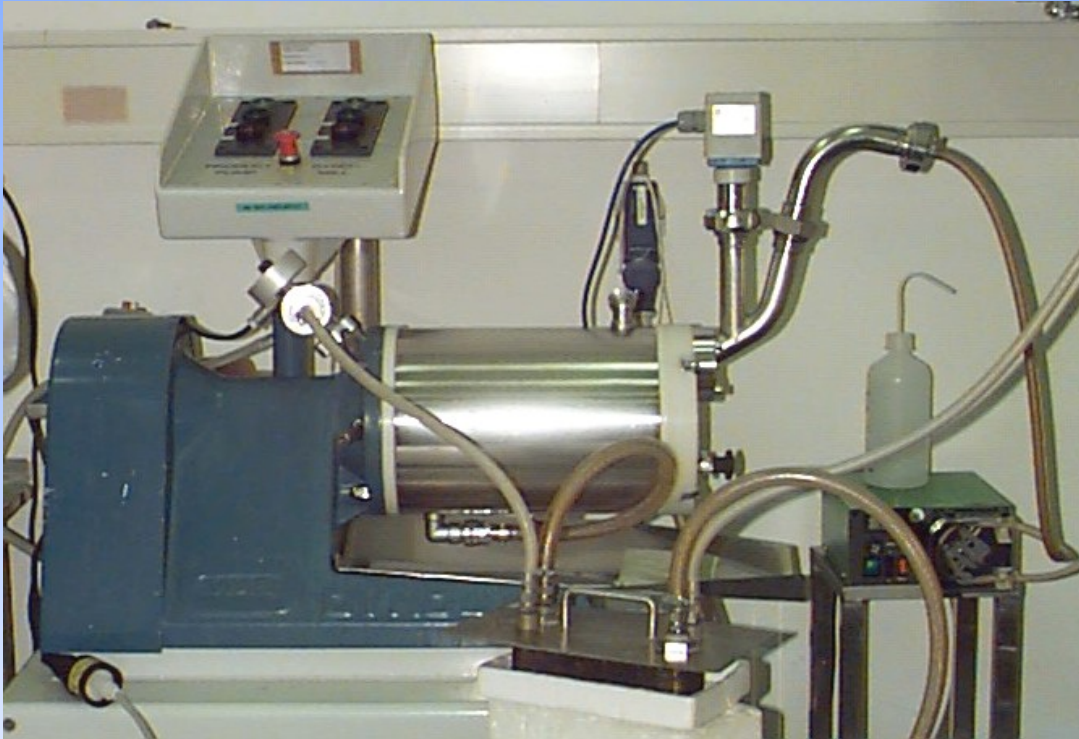
Luivac[®] Fermentation Plant



Luivac[®] Disc Centrifuge



Luivac[®] Dyno Mill and Filling Unit



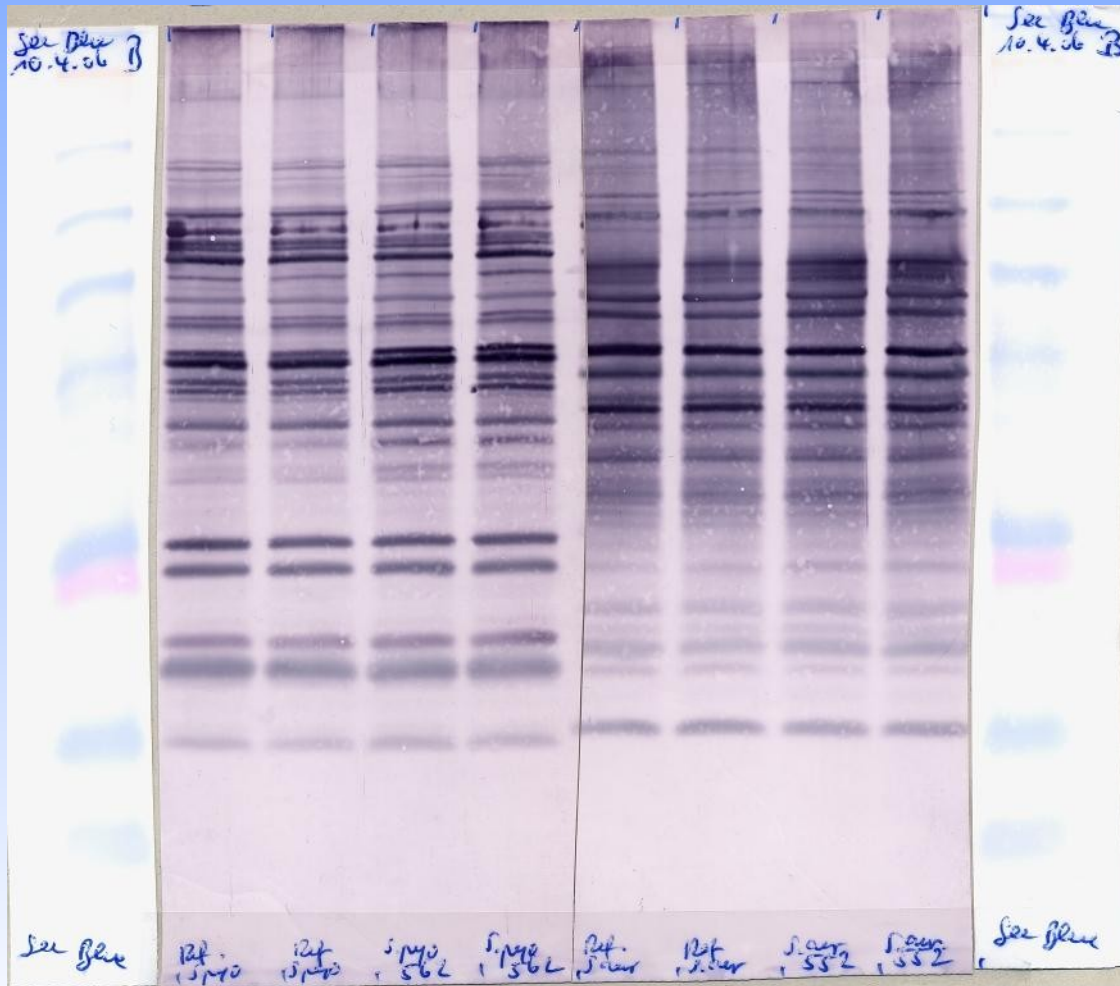
Luivac[®] Filling Vessel

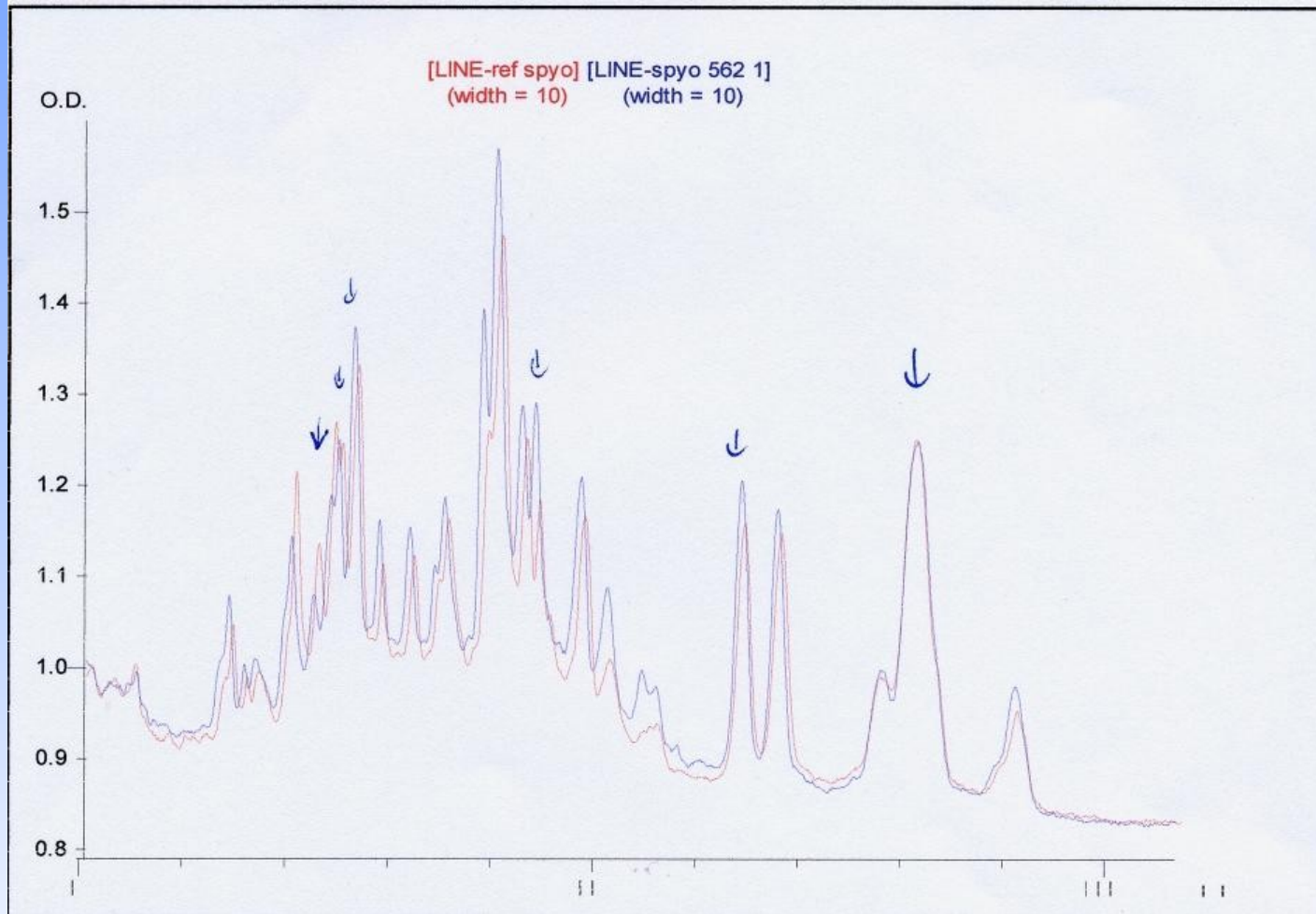


Quality Control Gel Electrophoresis

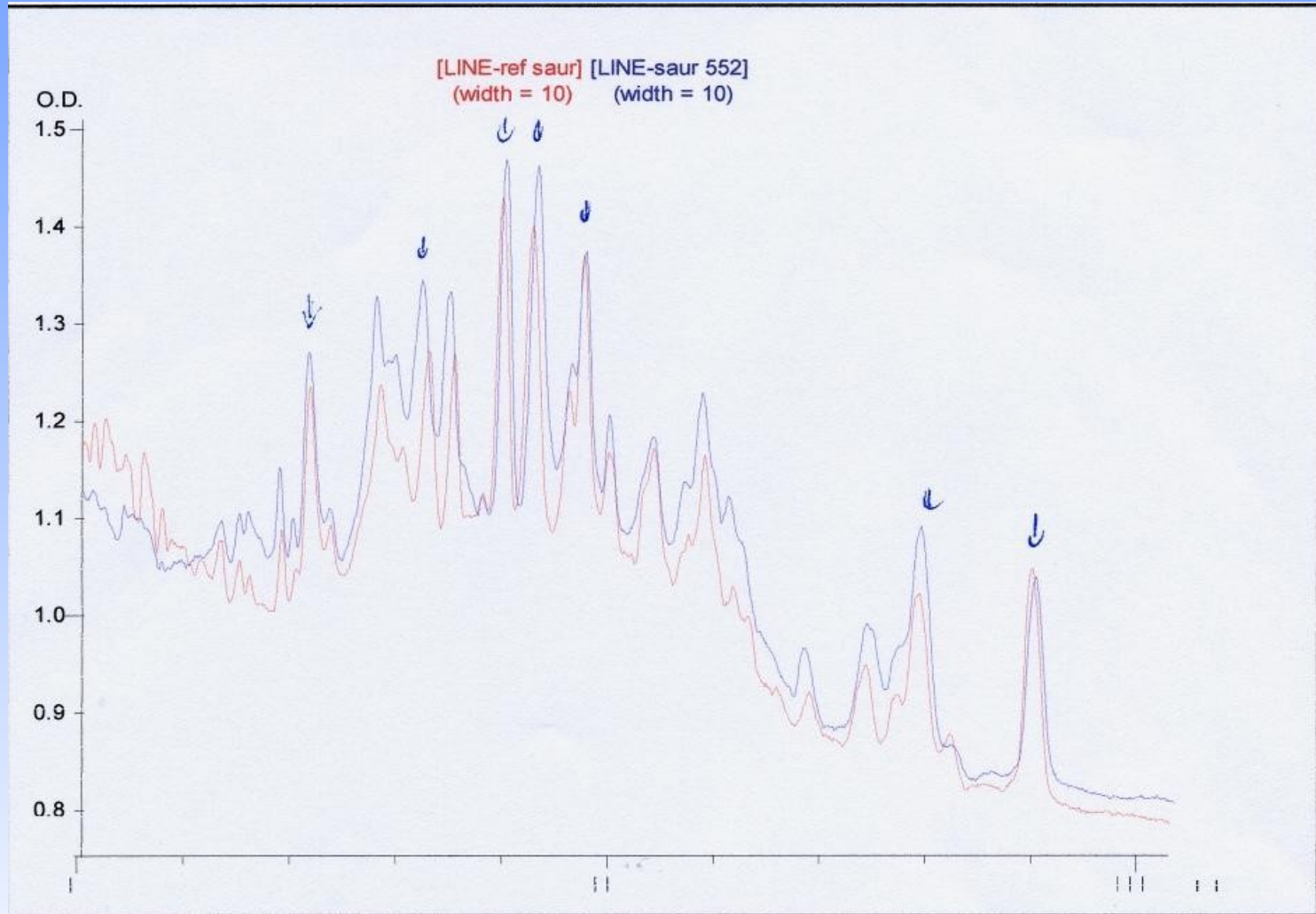
S. Pyogenes

S. Aureus

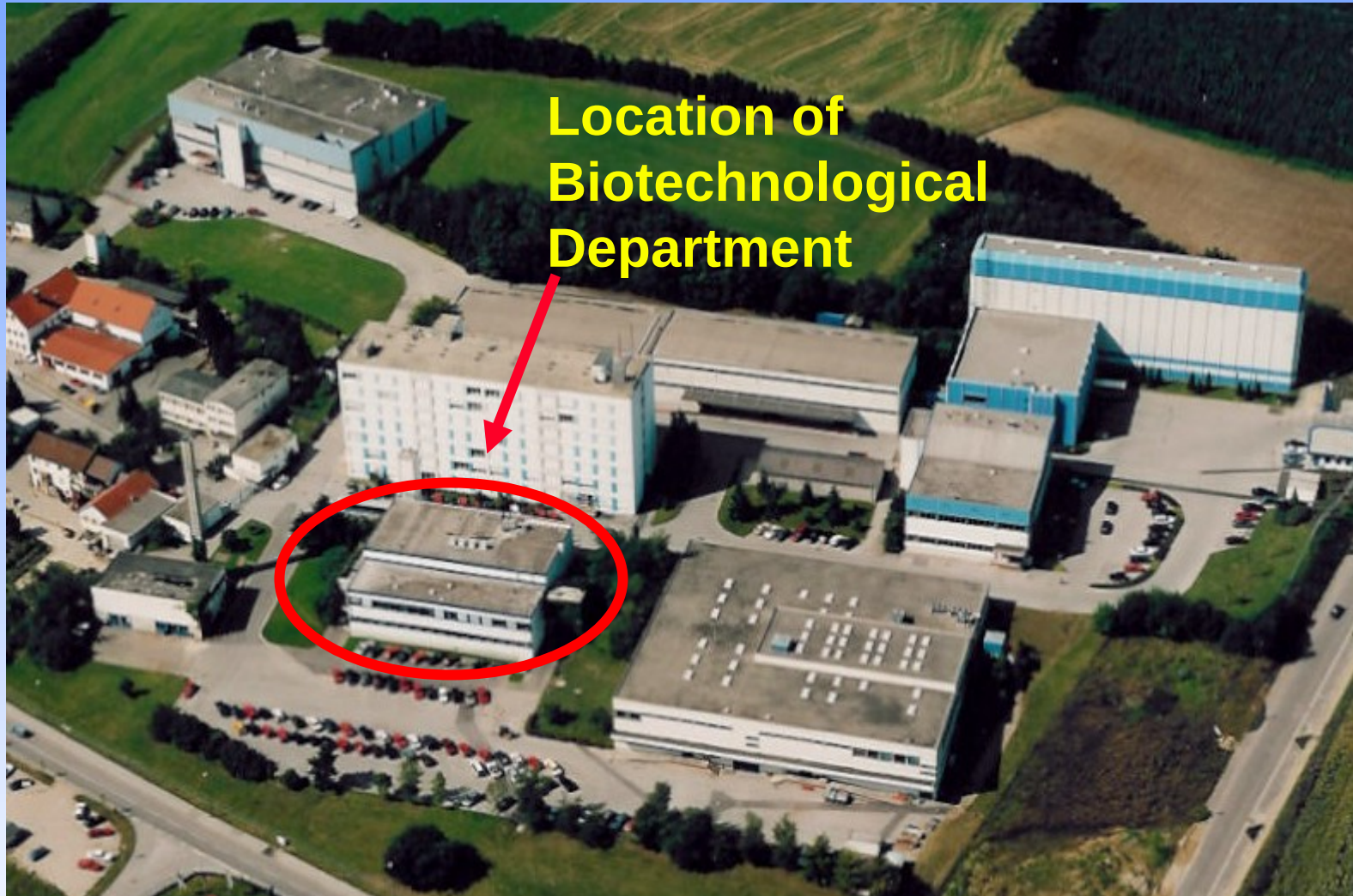




Scan von *S. pyogenes*, Blot, 05/34556201



Scan von *S. aureus*, Blot, 05/34555201



Luivac[®] tablets

Trademark Luivac[®] in Europe:

Austria, Czech Republic, Germany, Italy, Latvia, Lithuania, Luxembourg, Poland, Portugal (Paspal oral), Romania, Slovakia, Switzerland

and Overseas:

Argentina, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, el Salvador, Guatemala, Honduras, Lebanon, Mexico, Panama, Peru, Philippines, South Korea, Venezuela