Health & Research

Innovating the future...
Index

- Company profile
- Export Countries
- Product Range: clinical diagnosis
- Technology
- New Launching:
  - Shigella
  - Shigella dysenteriae
  - Calprotectin
  - HAV
- Products pipeline
  - Norovirus
  - Entamoeba histolytica
  - S. pneumoniae
- Conclusions
Company profile
Company profile I

- Established in Madrid since 1994 as developer and marketer of generic drugs under the name of Vegal Farmacéutica, S.L.

- Brand: H&R

- Field: Biotechnology applied to in Vitro diagnostic use

- Product range: Rapid test for diagnosis

- Worldwide presence through our exclusive distributors network

- Expertise Quality Assurance & Regulatory Affairs team to support our partners with the increasing regulatory requirements
Company profile II

- High qualified R&D Department always innovating to offer the last and most reliable products to the most exigent industry

- High technical products based in our high quality starting materials

- Regulatory compliance: European Directive 98/79/EC for In Vitro Diagnostics Devices

- Full control of the process: from the monoclonal antibody development until the commercialization of the test

- 100% reinversion of the turnover in the development of the company
Export countries
Export countries

- UAE
- Russia
- Chile
- Kenya
- Kuwait
- Italy
- Morocco
- Georgia
- Bulgaria
- China
- Slovenia
- Taiwan
- Thailand
- El Salvador
- Afghanistan
- Syria
- Saudi Arabia
- Peru
- Rumania
- ....
Product range
Product range – antigen detection of Enteric pathogens in fecal samples

- VIRUSES:
  - ROTAVIRUS
  - ADENOVIRUS
  - ROTA-ADENO
  - ASTROVIRUS
  - ENTEROVIRUS
  - HEPATITIS A (HAV)

- BACTERIA:
  - E.COLI O157:H7
  - CAMPYLOBACTER
  - SALMONELLA
  - LISTERIA
  - SHIGELLA

- PARASITES:
  - CRYPTO
  - GIARDIA
  - CRYPTO-GIARDIA

Format: 30 card test kit with stool vials
Product range – antigen detection of Respiratory pathogens in nasopharyngeal samples

- AVIAN FLU
- SWINE FLU
- INFLUENZA A
- INFLUENZA A+B
- RESPIRATORY SYNCYTIAL VIRUS (RSV)
- ADENOVIRUS RESP.
- RSV-ADENO
- RESPIRATORY
- STREPTOCOCCUS A
- LEGIONELLA

Format: 25 card test kit with swabs
Product range – Gastrointestinal & Bowel

- H. PYLORI antigen
- CALPROTECTIN
- LACTOFERRIN
- FOB
- FOB-TRANSFERRIN

Format: 30 card test kit with stool vials
Product range – hCG & DOAs

- hCG S&U
- DOAs:
  - MOP (OPIATES)
  - COC (COCAINES)
  - MET (METHAMPHETAMINE)
  - AMP (AMPHETAMINE)
  - MTD (METHADONE)
  - MDMA (ECSTASY)
  - THC (MARIJUANA)
  - BZO (BENZODIAZEPINES)
  - BAR (BARBITURATES)

Format: 40 card test kit
Product range – Dry positive and negative controls in sterile swabs

- ROTAVIRUS
- ADENOVIRUS
- ASTROVIRUS
- ENTEROVIRUS
- HEPATITIS A (HAV)
- E.COLI O157:H7
- CAMPYLOBACTER
- SALMONELLA
- LISTERIA, SHIGELLA
- CRYPTO, GIARDIA
- INFLUENZA A
- INFLUENZA A+B
- RSV
- ADENOVIRUS RESP.
- STREPTOCOCCUS A
- LEGIONELLA
- H.PYLOREI
- CALPROTECTIN
- LACTOFERRIN
- FOB
- TRANSFERRIN
- HCG

External Quality Controls: extract pre-dried for a better performance

Format: 30 card test kit
Technology I

- Technique: immunochromatographic assay for qualitative detection
- Format: 25 – 30 – 40 cards per kit
- Definition of colour: use of latex for a precise interpretation
Lateral flow technique

1. The membrane is pre-coated with monoclonal antibodies on the test lines region.

2. During testing, the sample reacts with the particles coated with antibodies which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action.
3. In case of positive result, the specific antibodies present on the membrane will react with the mixture conjugate and generate colored lines.

4. A control line band always appears and serves as verification that sufficient volume was added, that proper flow was obtained and as internal control for the reagents.
Technology IV

Fecal sample

1. Faeces
2. Insert sample
3. Mix
4. Result

Easy performance and interpretation

Nasopharyngeal sample

1. Swab
2. Mix
3. Place in tube
4. Result

RESULT INTERPRETATION
- Negative
- Influenza A Positive
- Influenza B Positive
- Influenza A+B Positive

10 min
Technology V

- Samples easy to collect: faeces / urine / nasopharyngeal
- Easy to perform. Simple
- Quick. 5-10 minutes result.
- Easy to interpret. Not necessary equipment
- Excellent specificity and sensitivity value.
- Excellent *mouse monoclonal antibodies*
New launchings
New launching - Calprotectin

- Protein that has bacteriostatic and fungistatic properties that **can be easily measured in faeces**.

- The main diseases that cause an increased excretion of fecal calprotectin are inflammatory bowel diseases (i.e.: Crohn’s disease, ulcerative colitis…) and neoplasm (cancer)

- **Elevated concentrations of fecal calprotectin** have been demonstrated in numerous studies of patients with **inflammatory bowel disease (IBD)**.

- Fecal calprotectin has been shown to consistently differentiate IBD from irritable bowel syndrome because **it has excellent negative predictive value** in ruling out IBD in undiagnosed, symptomatic patients.

- **Measurement of fecal calprotectin** as a biochemical test for inflammatory bowel disease **could replace the need for invasive colonoscopy** or radio-labelled white cell scanning in many clinical scenarios
New launching - HAV

- All age group are susceptible to HAV.

- Faecal-oral route transmission
  - Diarrhoea seems to be the first symptom of HAV.

- Takes between 2 and 6 weeks to produce symptoms. 2 weeks time to protect your liver.

- People who do not have symptoms can still spread the virus
  - Person-to-person spread.

- Children play an important role in spreading HAV:
  - The ones most likely to become infected, as they rarely have symptoms
  - Silent source of infection for others

- Infection with HAV is known to occur throughout the world.
  - Travellers to endemic areas.

- Costs associated with hepatitis A are substantial.
New launching – Shigella and Shigella dysenteriae

- **Shigella** is a bacteria closely related to *Escherichia coli* and *Salmonella*

- **Serogroup**:
  - Serogroup A: *S. dysenteriae* (12 serotypes)
  - Serogroup B: *S. flexneri* (6 serotypes)
  - Serogroup C: *S. boydii* (23 serotypes)
  - Serogroup D: *S. sonnei* (1 serotype)

- Shigella infection is typically via ingestion (fecal–oral contamination)

- The most common symptoms are diarrhea, fever, nausea, vomiting, stomach cramps and flatulence. The stool may contain blood, mucus, or pus.

- Symptoms can take as long as a week to show up, but most often begin two to four days after ingestion. Symptoms usually last for several days but can last for weeks. Shigella is implicated as one of the pathogenic causes of reactive arthritis worldwide.
Product portfolio
Product Portfolio: Norovirus

- Comes to complete our gastroenteritis current rapid tests portfolio: *Rotavirus, Adenovirus, Astrovirus, Rota-Adenovirus*.

- Everyone is susceptible to Norovirus infection.

- Found in stool and vomit of infected people.

- **Highly infectious.** Once introduced, infection spreads very rapidly by either person-to-person transmission or through contaminated food.

- Outbreaks may occur in group settings: hospitals, facilities, prisons, cruise ships...

- **Causes approximately 90% of epidemic non-bacterial outbreaks of gastroenteritis around the world.**

- Acute gastroenteritis is a common cause of morbidity and mortality worldwide.
E. histolytica is estimated to infect about 50 million people worldwide.

E. histolytica, as its name suggests (histo-lytic = tissue destroying), is pathogenic and infection can lead to amoebic dysentery or amoebic liver abscess.

The active stage exists only in the host and in fresh loose feces; cysts survive outside the host in water, in soils, and on foods, especially under moist conditions on the latter.

When cysts are swallowed they cause infections by excysting (releasing the trophozoite stage) in the digestive tract.

Symptoms can include fulminating dysentery, bloody diarrhea, weight loss, fatigue, abdominal pain, and amoeboma.

The amoeba can actually 'bore' into the intestinal wall, causing lesions and intestinal symptoms in different vital organs of the human body: the liver, the lungs, brain, spleen, etc.

A common outcome of this invasion of tissues is a liver abscess, which can be fatal if untreated.
Product Portfolio : S. pneumoniae

- Bacteria member of the genus Streptococcus.

- *S. pneumoniae* is **normally found** in the nasopharynx of 5-10% of healthy adults, and 20-40% of healthy children.

- It attaches to nasopharyngeal cells through interaction of bacterial surface adhesins.

- This normal colonization **can become infectious** if the organisms are carried into areas such as the Eustachian tube (**causing otitis media or sinusitis**) or if spreads to the blood stream (**where it can cause bacteremia**).

- Also if carried to the meninges, joint spaces, bones, and peritoneal cavity, may result in meningitis, brain abscess, septic arthritis or osteomyelitis.

- **Pneumonia occurs if the organisms are inhaled into the lungs** and not cleared.
Conclusions
Conclusions

- Tests easy to perform with a very quick result timing
- Not equipment needed → cost and time saving
- Excellent *mouse monoclonal antibodies*
- Excellent specificity and sensitivity value
- High quality products and personalized customer service
- Expertise dedicated team with specific training: R&D, QA&RA, sales force, marketing team
- Innovation oriented strategy
Thank you!