

# ITAMA

## *ICT Tools for the diagnosis of Autoimmune diseases* *in the Mediterranean Area*



Christopher Barbara  
Clinical Chairman



# What is ITAMA?

- ITAMA is a multidisciplinary project, part financed by the INTERREG V-A Italia-Malta program under the leadership of the Department of Physics and Chemistry of the University of Palermo.
- Other partners involved are the Malta Ministry for Health, Mater Dei Hospital, AcrossLimits Ltd and the University of Messina.
- ITAMA started in 2018 and will end in 2022 (due to a 10month extension resulting from COVID pandemic delays).
- Coeliac Disease (CD) condition is still underdiagnosed and leads to a long list of complications which may be prevented by an early diagnosis
- Biopsy is currently the Gold Standard for diagnosis of coeliac disease

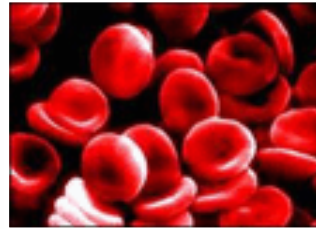


# Project Aim

- To verify the effectiveness of Point of Care Test (PoCT) - less invasive methods to diagnose Coeliac Disease especially in children of paediatric age.
- Raise awareness about the coeliac condition and study the disease in two neighbouring countries sharing a very similar diet.
- Improve the diagnostic process from the concept of test accuracy to utility of the test (predictive value), with the support of ICT tools, currently not available in the scientific community for this pathology.
- Define tools for technology transfer and/or process innovation in the healthcare sector.



# The Pathology Department @MDH



- About 6 million tests per year
- 2150 different tests performed
- Employs about 400 staff
- About 200 rooms (labs and offices)
- Yearly Expenditure:
  - **€4.5 million on salaries**
  - **€3.2 million on test kits/consumables**



# Pathology Dept role in ITAMA

- Sourcing PoCTs
- Sourcing professionals to perform tests
- Collecting physical copies of symptoms questionnaires
- Working with Paediatric Team to coordinate blood tests for children whose PoCT result positive
- Coordinating further testing of blood tests in Palermo (Buccheri La Ferla Hospital)
- Supporting all project testing logistics processes as necessary



# Maltese Eating Habits

- Wheat products (bread and pasta), and rice are the major source of energy in the Maltese diet contributing a third to the total energy.
- The staple cereal in Malta is wheat, mainly as bread (78%) and then, mainly as local white bread (99%).
- Pasta contributes 11% to the total purchase of cereal products .

## Reference:

**Bellizzi, M.** (1992). *The Maltese Food Revolution : An analysis of the eating habits in Malta.*



# Coeliac Disease Clinical Case Recognition in Malta

- Prevalence of CD based on clinical diagnosis & GFD:  
1.9/1000 (1 in 526 gen. Pop<sup>n</sup>)  
Older age at diagnosis of paediatric cases

*Ref: C. Vella, V. Grech Ind. J Peds 2004*

- Analogous population-based study (clinical presentation / GFD) from Sicily – prevalence 1.65/1000; adjusted actual standardized rate 3/1000

*Ref: Magazzú G, et al. Acta Paediatr. 1994;83(10):1065-9*

- Worldwide average 1:3345 on clinical, 1:266 on screening data

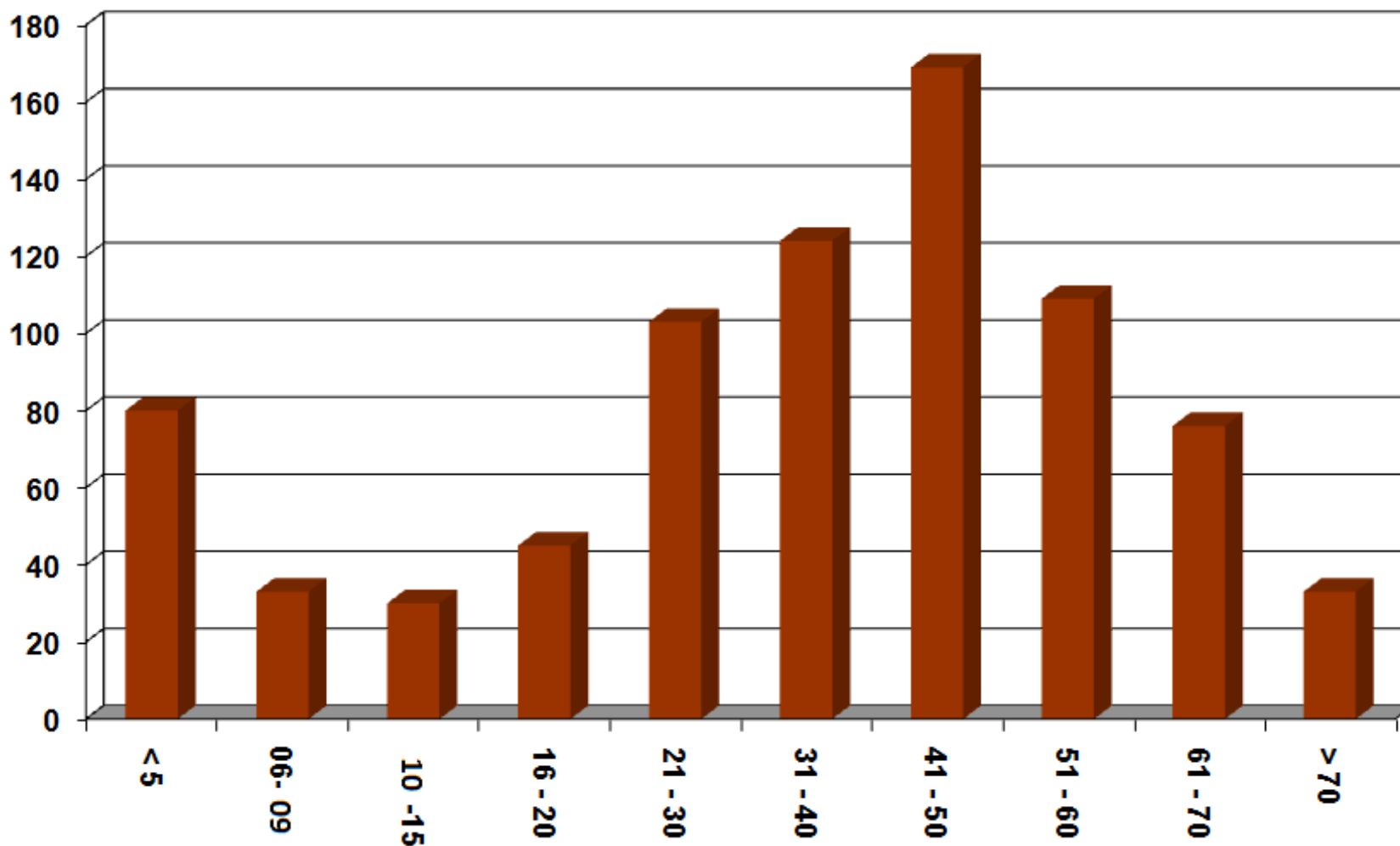


# Statistics and distribution of Coeliac Disease Diagnosis in Malta

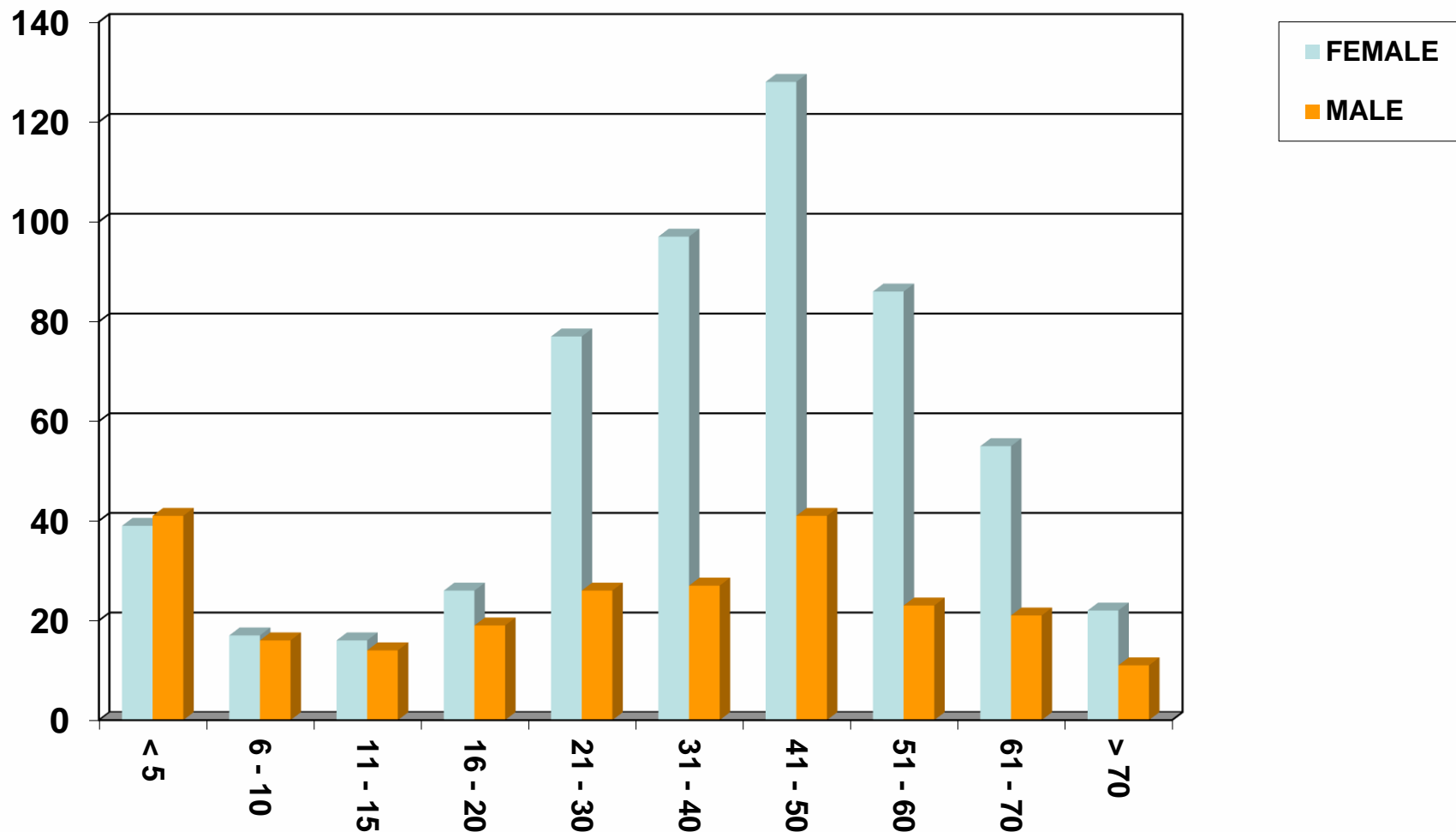




# Age at diagnosis distribution



# Age at diagnosis by gender distribution



# Vouchers for people certified with CD



Over 16

1,114

Under 16

291

**Grand Total**

**1,405**



# The Testing Process in the Schools of Malta for children aged 4-12 years



# Step 1

**Tick ✓ If your child has or ever had any of the following medical conditions:**

	YES	NO	DON'T KNOW		YES	NO	DON'T KNOW
1. Persistently tired/ weak/low energy				13. Repeatedly complains of abdominal pain			
2. Immunodeficiency				14. Thyroid problems			
3. Vomiting (more than 1 episode per month in last 3 months)				15. Abdominal distention / bloating, flatulence			
4. Liver problems				16. Irregular bowel habits			
5. Diabetes type 1				17. Alopecia (hair loss)			
6. Anaemia (pallor, low blood level)				18. Vitiligo (white skin patches)			
7. Rheumatoid Arthritis				19. Down's, Williams or Turner's syndrome			
8. Renal problems				20. Recurrent mouth ulcers			
9. Epilepsy				21. Difficulty with balance/walking			
10. Severe dental decay				22. Poor weight gain, anorexia, weight loss			
11. Mood changes				23. Short stature/growth failure			
12. Persistent loose stools				24. Weak bones			
				25. Constipation			

**Does any family relative suffer from Coeliac Disease?**

YES  NO  DON'T KNOW

If yes, please specify the relationship to the child:

Father  Mother  Sister/brother  Maternal Grandfather  Maternal Grandmother   
Paternal Grandfather  Paternal Grandmother  Other: \_\_\_\_\_

Parents fill in a form with symptoms that their children might be suffering from.



# Step 2

MUMN nurses do the PoCT on children in their own school and record PoCT results and questionnaire data on ITAMA app.



# Step 3

- Physical questionnaires and used PoCTs are returned to the Pathology Lab for storage.
- Questionnaires of positive PoCTs are identified and parents called for follow up.
- Children with positive PoCT are called for an intravenous blood test at Mater Dei Paediatric Day Care.

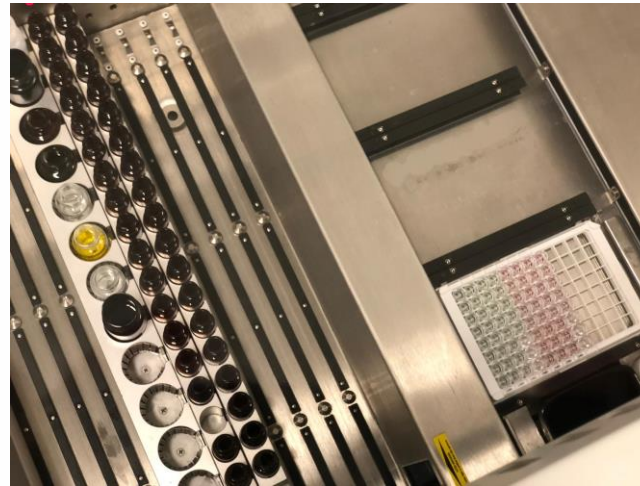




# Blood tests @ Pathology lab in Malta

## anti-TTG (ELISA)

- Most sensitive test but less specific (used as a screening tool)
- ELISA technique – fast, high throughput, quantitative technique
- <9 IU/mL negative, 9.1-16.0 IU/mL borderline, > 16.1IU/mL positive results
- Fully automated technique
- Results logged in the ITAMA app by MDH Paediatricians

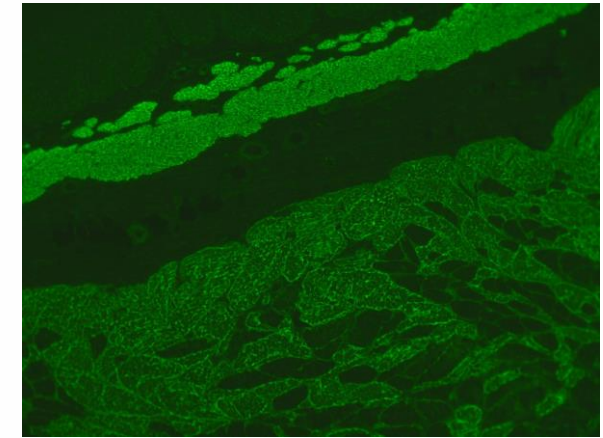
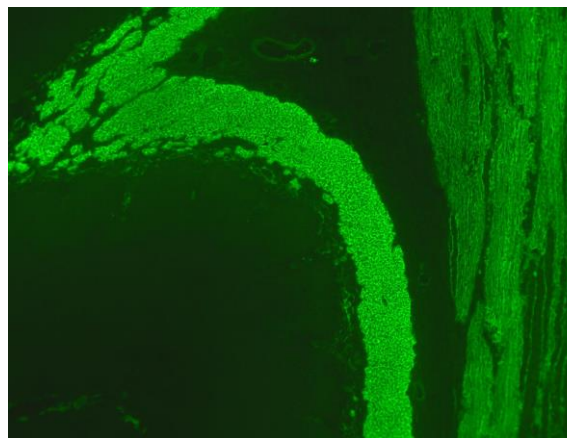
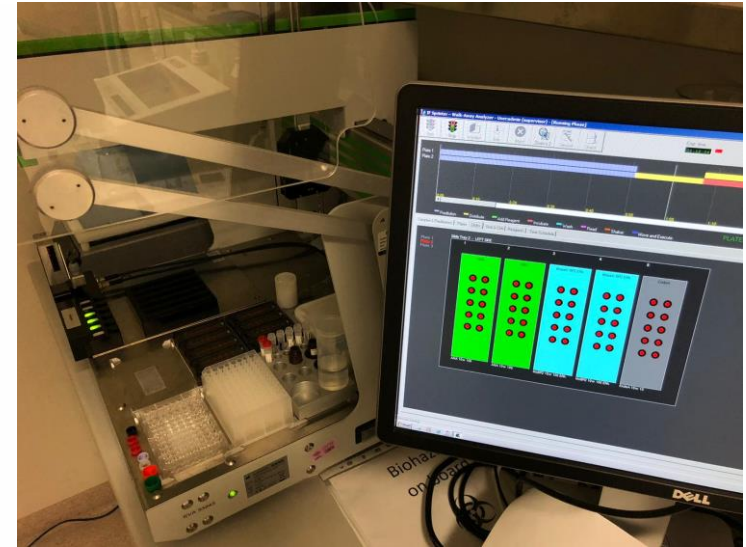
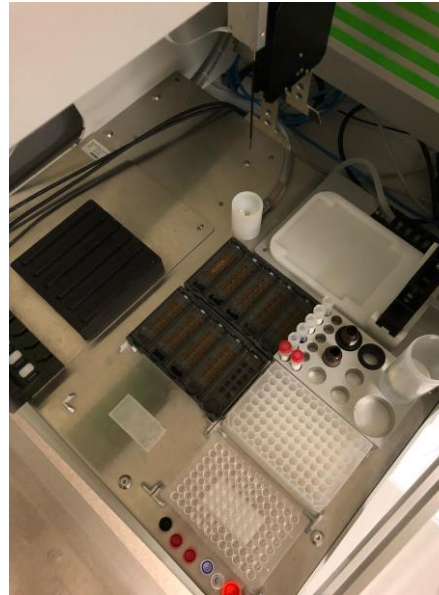




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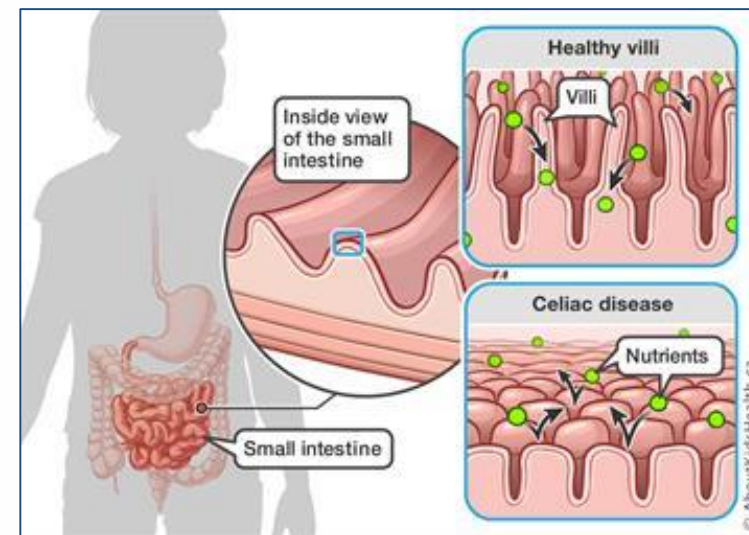
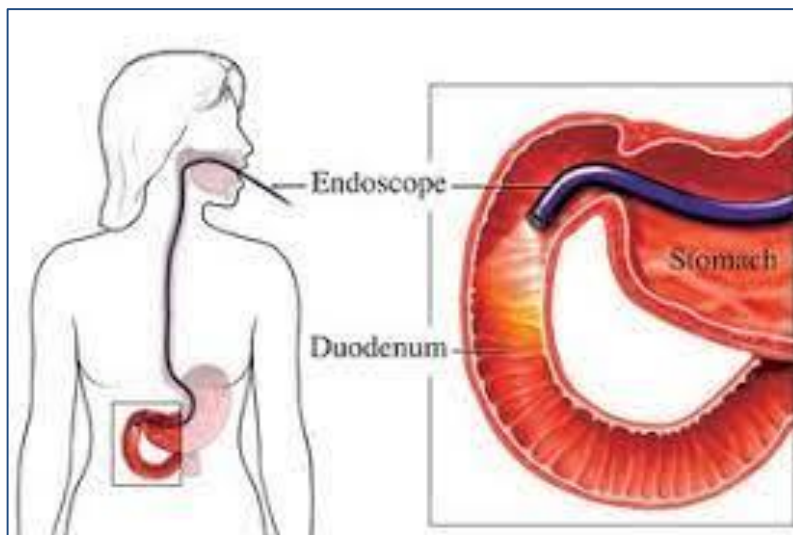
## AEA (EMA)

- More specific technique, less sensitive (used to confirm initial anti-TTG result)
- EMA technique – indirect immunofluorescence
- Semi-automated technique – manual screening of slides on the fluorescent microscope
- Results issued as: Negative or Positive +/-/+/++
- Results logged in the ITAMA app by MDH Paediatricians



# Step 4

- Patients with positive anti-TTG and AEA will be referred for endoscopy and biopsy at MDH



# Step 5



- The blood samples taken in Malta are frozen and shipped to Buccheri La Ferla Hospital in Palermo.
- Similar blood tests as done at MDH in Malta will be repeated in Palermo as a double diagnosis.





# Project Numbers as at 2<sup>nd</sup> July, 2021

Number of PoCTs performed

**18,360**

Number of confirmed Positives

**131**

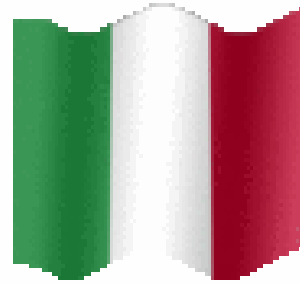
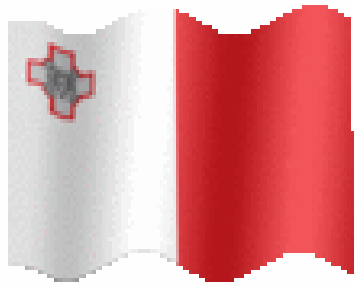
Number of blood tests done

**93**

Number of endoscopies done

**1**





 **Interreg**  
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Fondo Europeo di Sviluppo Regionale  
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# Thank You For Your Attention

